S. HRG. 103–429

CATARACT SURGERY: GUIDELINES AND OUTCOMES

Y 4. AG 4: S. HRG. 103-429

Cataract Surgery: Guidelines and Ou...

WORKSHOP

BEFORE THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

WASHINGTON, DC

APRIL 21, 1993

Serial No. 103–5

APR 19 1994

Printed for the use of the Special Committee on Aging

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CATARACT SURGERY: GUIDELINES AND OUTCOMES

WEDNESDAY, APRIL 21, 1993

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The workshop was convened, pursuant to notice, at 10:43 a.m., in room 428A, Russell Senate Office Building, Ms. Nancy Smith [moderator of the workshop] presiding.

Present: Senators Pryor and Burns.

OPENING STATEMENT OF SENATOR DAVID PRYOR, CHAIRMAN

Senator PRYOR. Ladies and gentlemen, thank you for coming.

I'm David Pryor and I chair the Special Committee on Aging. I'm very honored that we have such a wonderful turnout this morning.

I'm not going to be able to stay. I'm going to yield in a moment to my friend, Nancy Smith, formerly associated with the office of the late Senator John Heinz.

Nancy, if I'm not mistaken, it was 1989 when Senator Heinz and I, after looking at what we thought were some rather large increases in Medicare expenditures for surgery and outpatient services, Senator Heinz and I decided that we might find it timely to make a request of the General Accounting Office to look at cataract surgery.

We want to make it very clear that this is in no way an attempt to bash ophthalmologists or doctors in any way, shape, or form. This is, once again, an attempt to find the facts after visiting with many, many patients who have had cataract surgery.

We also want to make certain that the purpose of this report that we find today released is to educate patients, to educate our general public, to discuss the guidelines that we're looking at now, to also embark on this gargantuan task of cost containment as the President's Health Care Task Force, the White House, and the Congress begin this very monumental mission, and also how we might improve the quality of care and to help control some of these costs.

We have invited some true experts in the field and some of the colleagues I've worked with on many other issues in the past. We're just so appreciative of their help and support in helping us to gather this information.

I'm going to yield at this time to Nancy. Is that the way we're doing our agenda this morning? We have a vote in just a few minutes and I've got some business over in the Capitol before that vote occurs, so I'm going to have to yield and leave our good staff people

who will help gather this information that you and your colleagues impart.

We're very appreciative of all of your coming. Thank you very much.

STATEMENT OF NANCY SMITH, DIRECTOR OF THE EXECUTIVE OFFICE OF THE AMERICAN COLLEGE OF PHYSICIANS, WORKSHOP MODERATOR

Ms. SMITH. Good morning, Senator Pryor, members of the panel, ladies and gentlemen, and staff.

It's a pleasure to be back here, both for personal and professional reasons. You did hear me recognize the staff for, as Senator Pryor said, I was formerly a member of John Heinz' staff.

Senator Pryor, I'm glad you stayed because I wanted to commend you, Senator Cohen, and the Committee for continuing with the good work on quality assurance that Senator Heinz as well as this Committee are known for. It's personally very gratifying and I'm here largely in Senator Heinz' honor. This is as much a personal as a professional event for me.

Professionally, I'm Director of the Executive Office of the American College of Physicians. The College is the largest medical specialty organization in the country, if not the world. We have 80,000 member internists. The College has for years been involved in the development of practice guidelines and an advocate of incorporating functional assessment as well as patient involvement in treatment decisions, especially for geriatric patients.

As we know very well, the primary beneficiaries of cataract surgery are, in fact, older persons. These same people are the primary people at risk of unnecessary care.

In my view, this workshop today is an important step in looking at how better to inform both the science and the art of medicine. Today, we will hear from our panelists and we will also have an opportunity to hear from you.

We have four panelists, each of whom will speak for 10 to 12 minutes, and I will hold them to that, because an important part of this format is, in fact, to leave ample time for you to raise questions and comments to the members of the panel.

We will begin now. My role is to moderate and I'm not going to prolong any opening comments.

Our first speaker today is Ms. Eleanor Chelimsky, the Assistant Comptroller General of the General Accounting Office, Evaluation and Methodology Division. She will report on the findings of the GAO report which is being released today.

STATEMENT OF MS. ELEANOR CHELIMSKY, ASSISTANT COMPTROLLER GENERAL, GENERAL ACCOUNTING OFFICE, PROGRAM EVALUATION AND METHODOLOGY DIVISION

Ms. CHELIMSKY. Thank you so much, Nancy.

It's really a pleasure to be here this morning to talk about the work this Committee asked GAO to do.

Let me begin by introducing the people who are here with me today: George Silberman, who heads our health policy work in the Program Evaluation and Methodology Division and Dr. Eric Peterson who conducted the study for GAO.

As you know, our full report[1] is being released today and you also have my official statement for the record, so I would just like to highlight a few facts about our study and then layout its findings and policy implications.

First, the study is based on a survey we conducted of Medicare patients who had undergone cataract surgery. The survey responses describe, from the patients' perspectives, their experiences with that surgery. The focus is on the extent of their eye symptoms and functional limitations, both before and after surgery.

These data allowed us to assess both the appropriateness of the surgery in terms of patient functional impairment before the surgery, and surgery outcomes, that is, changes for better or worse in those symptoms and functions after the surgery took place.

I believe the study is useful for a couple of reasons. First, the subject is important. It's important because a large number of cataract surgeries are now performed each year at considerable cost to Medicare, more than 1,350,000 operations in 1991 with an estimated price tag of $3 billion. It's important because these already big numbers are expected to multiply over the next two decades as the baby boom generation enters the years when cataracts most often develop. It's also important because 95 percent of cataract surgeries are now performed on an outpatient basis with much less systematic monitoring of costs and benefits to patients than would be the case in an inpatient setting.

Second, the study is useful because it produces new information with regard both to treatment effects and to the medical necessity for the surgery in the first place.

Third, the information was generated using an unusual source, the patients themselves, and I believe the success of this datagathering opens the way for greater use of patient data in both clinical decisionmaking and quality assurance generally.

Finally, the study has implications for health care reform in that the analysis of patient data, when it's appropriate, raises new possibilities for incorporating more of the experience of patients into clinical and administrative decisions.

Senator PRYOR. Senator Burns, we're just so proud you're here. I've come to listen for just a moment. I've already opened our meeting and then I'm going to be leaving in just a moment.

Senator Burns, by the way, has just had cataract surgery and he may want to comment on some of this.

This is the General Accounting Office giving its report, Senator Burns. You may want to wait until they finish, whatever you desire.

Senator BURNS. May I listen just for a moment?

Senator PRYOR. Surely.

Ms. CHELIMSKY. Let me now get into our findings which are essentially two.

First, with regard to outcomes, and let me insist on this point, the majority of patients did well, very well. You may want to look at the table that's over here in which you can see that, of the patients we looked at, with regard to their functional situation, 74 percent did better than before the operation. With regard to symp-

[1] See appendix, p. 65.

toms, 71 percent did better; and with regard to both functions and symptoms, 66 percent did better.

By functions, I mean watching TV, reading, driving, things of that sort. Symptoms are: blurred vision, sensitivity to glare, double vision, itching, floaters, feeling of something in the eye. In other words, between two-thirds and three-quarters of patients were better off after surgery.

Also, the incidence of serious adverse events was quite low as you can also see and in every category, symptoms, functions, both of these taken together, there were few patients who reported being worse off after the surgery than before. Still, there were enough of these patients, around 5 percent, to show that good quality assurance mechanisms are still warranted for cataract surgery.

Our study also shows that patients who were worse off before surgery did better afterwards. This confirms what was generally expected before we began our study.

Our second finding concerning the appropriateness of surgery was unexpected. The study shows that, depending on the criterion you adopt for medical necessity, moving from whether the patient has any level of problem before the surgery to more than slight functional impairment, there could be from 2.5 percent to 24 percent of unnecessary cataract surgeries currently being performed. You may want to take a look at this chart.

What we did was use four different potential criteria for establishing inappropriateness. In the first one, the first line where you see the 2.5 percent at the far right, we would say that surgery is inappropriate when the patient has no problem with either functions or symptoms prior to surgery. That, of course, is a very permissive criterion, no problem or symptom at all, and we found that 2.5 percent of our sample would have been considered inappropriate even by that criterion.

The second criterion would be that surgery is inappropriate when the patient has no presurgery problem with functions alone, although there may be problems with regard to symptoms. When we applied that criterion to our sample, we got 6 percent of inappropriate surgery.

When we became more restrictive and said surgery would be inappropriate when there are no more than slight problems with either functions or symptoms, we got 16.3 percent and when we moved to the most restrictive criterion, we found 24 percent of inappropriate surgeries possible.

We can't be any more precise than this for two reasons. First, the lack of firm criteria forced us to make a number of estimates rather than one. Second, we collected data in only four States—California, Massachusetts, Pennsylvania and Texas—and our findings are generalizable exclusively to those States and not to the Nation. So we can merely hypothesize what the proportions of surgery may be nationwide that are performed without problems or with only slight problems experienced by patients.

With regard to the data we have, a number of factors give us confidence in their validity and reliability. These are our high response rate and our investigation of nonrespondents; the large volume of surgeries in all four States; the lower likelihood of recall problems in this area than in others; and the fact that patients are

always the best source of information about how they feel and whether their situation has improved.

What are the implications for policy? I see two of them. First, if you hypothesize that our findings might be applicable nationwide, something that we don't know, and you use the guideline for medical appropriateness supplied by the American Academy of Ophthalmology; that is, functional impairment perceived by the patient in his or her daily life, then our study shows 6 percent of cataract surgeries as inappropriate which is, again, that second line.

This would equate nationwide to an unnecessary expenditure by Medicare in 1991 of about $200 million. Of course if the criterion were set more strictly, for example, if surgeries were considered appropriate only when patients perceived something more than slight difficulty in their functional activities—that's the fourth line there—then our study shows 24 percent as inappropriate, which translates to $800 million in unnecessary Medicare expenditure.

The second implication I see has to do with the use of patient data to achieve better treatment effectiveness and quality assurance. I would argue that the lack of these data is a problem for quality whenever medical necessity is even partially based on patient experience, but even further, our findings show that the systematic collection of patient data can be an important component of health care reform because it would allow administrators a rare opportunity to improve quality of care via fewer unnecessary interventions while simultaneously lowering or delaying costs.

Thank you, Nancy. That concludes my remarks.

[The prepared statement of Ms. Chelimsky follows:]

United States General Accounting Office

GAO

Testimony

Before the Senate Special Committee on Aging

For Release
on Delivery
Expected at
10:00 a.m.
Wednesday
April 21, 1993

CATARACT SURGERY

Patient-Reported Data on Appropriateness and Outcomes

Statement of Eleanor Chelimsky
Assistant Comptroller General
Program Evaluation and Methodology Division

GAO/T-PEMD-93-3

Dear Mr. Chairman and Members of the Committee:

I am pleased to be here today to present the results of a study we conducted at the request of this committee. The specific topic is cataract surgery, but I believe that GAO's findings in this relatively narrow area also have relevance to the broader field of health care reform. As the nation struggles with mounting costs and concerns over diminishing quality, the data I will present this morning show that opportunities exist for reducing the costs of health care while simultaneously improving its quality.

This morning we are releasing a report on our study that provides more details than I can present in the context of this statement. Instead, what I will give here today is an overview of the study and its objectives, methods, and findings.

OVERVIEW

A cataract is a clouding of the lens of an eye that typically develops slowly as people get older. Depending on what part of the lens is most affected, and how far along the process has gone, the effect on vision can range from minimal to catastrophic. In most cases, surgical removal of the obscured natural lens, usually combined with the insertion of an artificial lens implant, is the only treatment option available. Whereas cataract surgery was once invariably a procedure performed on an inpatient basis, the overwhelming majority of cataract surgeries are now performed as outpatient procedures, either in hospital outpatient departments or in free-standing ambulatory surgical centers.

The shift of the locale for surgery from the hospital to the ambulatory setting has raised concerns regarding the mechanisms by which quality of care is monitored. Based on these concerns, this committee requested that we conduct a study evaluating quality assurance mechanisms under the Medicare program. The study, which focuses on cataract surgery, has a number of components, the most innovative of which is a survey of patients who have undergone cataract surgery. The objective of this survey was to gather information directly from patients on their experiences. We did this for two reasons. The first was because patients leave the ambulatory setting shortly after their surgery and there is no other systematic source of information on the

extent of morbidity (pain, swelling, infection, and so on) or benefit (improvements in vision) resulting from the procedure. Second, even if there were another source, patients have the greatest awareness and the most complete knowledge of the symptoms and functional impairments they have themselves experienced.

We sent our survey to 1,964 patients in California, Massachusetts, Pennsylvania, and Texas. We obtained usable responses from 1,488, or 76 percent. This rate is calculated from the total set of cases included in the random selection. Therefore, nonresponse includes all those for whom no survey results were obtained for any reason (death, mental infirmity, inaccurate mailing address, and so on).

For criteria for medical necessity, we used guidelines issued by the American Academy of Ophthalmology (AAO). These guidelines emphasize the importance of assessing both the effect of the cataract on the patient's usual activities and the clinical measurement of visual acuity in weighing the likely benefits of surgery against the risks of serious adverse outcomes. According to the guidelines, surgery is not appropriate unless there is evidence that the cataract has led to both clinically measured limitations in visual acuity and functional impairment perceived by the patient in his or her daily life.

Further, on February 25 of this year, the Agency for Health Care Policy and Research (AHCPR) announced a new guideline for the clinical management of cataracts in adults. This guideline, similar to AAO's, makes it clear that intervention is appropriate only when a functional impairment exists (that is, when some facet of daily living is constrained because of the cataract). Further, the guideline states that a "patient must understand the likely benefits and potential risks of undergoing cataract surgery." The data from our survey speak to each of these important issues and allow us to address two specific questions:

-- To what extent do patients undergoing cataract surgery experience positive results?

-- To what extent do surgeries meet the criteria established for medical necessity?

I will discuss our findings on each of these questions in turn.

OUTCOMES FROM CATARACT SURGERY

Although in individual cases other long-term outcomes may ensue, the central issue in outcomes measurement for cataract surgery is how much better patients can see once they have recovered from the operation. We addressed this issue by examining how much change was reported by our patient respondents in terms of both symptoms and functions. Tables 1 and 2 show the proportion of patients reporting that their functional capabilities and symptoms improved, stayed the same, or got worse. (Change in this analysis represents any increase or decrease in the extent to which a patient had difficulty with a functional activity or was bothered by a symptom.)

Table 1: Proportion of Patients Who Reported Their Visual Functioning Improved, Stayed the Same, or Worsened After Surgery

Activity	Better	Same	Worse
Watching TV			
Seeing picture at all	36.1%	60.6%	3.2%
Seeing colors	30.2	67.2	2.6
Recognizing people	44.4	51.9	3.7
Reading words on screen	62.3	33.3	4.4
Reading			
Headlines	32.0	65.7	2.3
Large print	24.1	73.9	2.0
Standard text	56.2	38.4	5.4
Telephone books	59.6	35.9	4.4
Driving			
Short distances in daytime	34.1	64.2	1.8
Long distances in daytime	47.0	48.9	4.1
Short distances at night	61.9	33.9	4.3
Long distances at night	61.1	35.7	3.1

Table 2: Proportion of Patients Who Reported Their Eye Symptoms Improved, Stayed the Same, or Worsened After Surgery

Symptom	Better	Same	Worse
Blurred vision	77.8%	18.8%	3.4%
Sensitivity to glare	53.1	35.8	11.1
Double vision	21.8	75.6	2.6
Itching	34.1	58.8	7.1
Floaters	44.8	50.8	4.5
Feeling of something in eye	37.9	55.8	6.2

As can be seen from the tables, a majority of patients reported an improvement in 5 of the 12 functional activities. The largest improvement was noted in reading words on television and driving at night, followed closely by reading telephone books and standard-sized text. Most of those who did not indicate improvement in a given activity remained unchanged, but between 2 and 5 percent said that they got worse after the surgery.

Much the same pattern emerged for symptoms. Improvement was most striking for blurred vision, where over three quarters said they got better. A little over half reported less sensitivity to glare, and somewhat less than half indicated improvement with "floaters." While most of the rest remained unchanged, between 3 and 11 percent reported getting worse. Sensitivity to glare was the symptom most likely to worsen after surgery.

Patients may improve in some symptoms or functions and worsen in others. To get a sense of how symptoms and functional abilities changed overall, we divided our respondents into four groups:

-- those reporting clear improvement (one or more items improved with none worsening),

-- those who experienced no change (no items either improving or worsening),

-- those reporting a clear deterioration (one or more items worsening with none improving), and

-- those with mixed results (some items improved and others worsened).

The distribution for functions alone, symptoms alone, and functions and symptoms together is shown in table 3.

Table 3: Cumulative Change in Symptoms and Functions: Cataract Patients Who Experienced Improvement, No Change, Worsening, or Mixed Outcomes

	Better	No change	Worse	Mixed
Functions	74.1%	9.7%	4.6%	11.7%
Symptoms	71.4	5.3	5.0	18.3
Functions and symptoms	65.9	1.7	2.4	30.0

Again, our data show that the results of cataract surgery were clearly favorable for a substantial majority of patients. In terms of change in visual functioning, symptoms, and both taken together, about three fourths to two thirds of the patients responding to our survey indicated some level of improvement with no offsetting worsening on another symptom or function. The next largest group, between 12 and 30 percent, improved in some areas and worsened in others. Uniformly adverse outcomes were limited to between 4 and 5 percent of patients for functions and symptoms and only a little more than 2 percent considering functions and symptoms together. Another 1.7 percent indicated no change for any symptoms or functions.

MEDICAL NECESSITY FOR CATARACT SURGERY

The guidelines issued by AAO on when cataract surgery should be performed specify three criteria as necessary:

-- the patient should perceive a visual disability, relative to the types of activities that he or she otherwise would normally undertake;

-- the patient's vision must be impaired (that is, the clinically measured best correctable visual acuity should be 20/50 or worse on the Snellen scale);[1]

-- the patient should have been informed of the risks and benefits of surgery and should have made his or her own decision that the benefits outweigh the risks.[2]

---

[1]Or 20/40 or worse with a patient's complaints of disabling glare.

[2]American Academy of Ophthalmology, "Cataract in the Otherwise Healthy Eye," September 16, 1989, p. 6.

Although our survey did not measure the frequency with which patients were involved in the decision to have cataract surgery (the third AAO criterion), we did collect data on the extent to which patients experienced symptoms and functional impairment prior to surgery. I will begin with the results reported by patients on the nature and extent of their presurgery symptoms.

Symptoms Prior to Surgery

Table 4 shows the proportion of patients who reported having each of the 6 symptome we asked about immediately prior to their cataract surgery and the extent to which they were bothered by them.

Table 4: Extent of Presurgery Eye Symptoms Reported by Patients

Symptom	Patient did not have symptom	Patient had symptom and was bothered			
		Not at all	A little	Moderately	Severely
Blurred vision	12.0%	5.2%	23.7%	31.7%	27.4%
Sensitivity to glare	23.4	6.0	25.4	26.3	18.8
Double vision	75.5	3.2	9.9	7.7	3.8
Itching	55.0	8.2	20.2	12.2	4.4
Floaters	40.3	15.4	24.1	14.4	5.7
Feeling of something in eye	52.5	6.9	20.8	13.1	6.7

Blurred vision and excessive sensitivity to glare were, as expected, the two most common presurgery symptoms reported by our respondents. They appeared in 88 and 77 percent of these patients, respectively. However, the extent to which these symptoms affected patients varied markedly. A few, 5 to 6 percent, had these symptoms but were not bothered by them at all. Another 25 percent, approximately, experienced little bother. Fifty-nine percent had moderate to severe difficulty with blurred vision, 45 percent with glare.

Table 5 presents the pattern when one looks for the most extreme presurgery symptom reported across all 6 possible symptoms. The intent is to show the proportion of patients who experienced different levels of "bother" because of their cataract-related symptoms. The table also shows the greatest degree of bother for just the three classic cataract symptoms--blurred vision, sensitivity to glare, and double vision.

Table 5: Highest Level of Presurgery Eye Symptoms Reported for Any of Six Symptoms[a]

Symptom	Patient did not have symptom	Patient had symptom and was bothered			
		Not at all	A little	Moderately	Severely
Most severe response among all 6 symptoms	3.0%	6.2%	20.9%	34.9%	35.1%
Most severe response among blurred vision, glare, and double vision	6.0	5.6	21.5	33.6	33.3

[a]The 6 symptoms are blurred vision, sensitivity to glare, double vision, itching, floaters, and a feeling of something in the eye.

As the table shows, only 3 percent of patients reported having no symptoms. However, almost 10 percent reported either not having had symptoms or not being bothered by them at all (3 plus 6.2 percent).

Functional Impairment Prior to Surgery

Let us turn now to functional impairment, the primary criterion for defining appropriate surgery in the AAO guidelines and in the more recent guideline from AHCPR. Both sets of guidelines are in accord that if daily life is not changed by the presence of a cataract, then surgery to remove the cataract is not justified. The reason for this is that although cataract surgery is usually safe, it does carry some risks, similar to most forms of surgery. This can be seen from our data in tables 1 and 2, showing that some patients did report getting worse after the surgery. In instances in which the surgery is unlikely to improve daily functioning, therefore, the logic is that these risks are not worth taking.

The data from our survey allow us to comment on the extent of functional impairment before surgery reported by patients undergoing cataract surgery. The responses to these questions, shown in table 6, indicate two overall patterns. First, except for the visually most stressful activities, the majority of patients reported relatively unimpaired eye function. Those experiencing little or no difficulty substantially outnumbered those having moderate to great difficulty in 8 of the 12 activities. For 2--reading words on television and driving short distances at night--about as many reported moderate to great difficulty as little or none. Only for reading telephone books and driving long distances at night did the group experiencing moderate to great difficulty clearly predominate.

Table 6: Extent of Presurgery Impaired Visual Functioning Reported by Patients

Activity	Amount of difficulty				Not applicable
	None	Little	Moderate	Severe	
Watching TV					
Seeing picture at all	57.1%	21.6%	14.0%	5.3%	2.0%
Seeing colors	63.8	16.8	10.7	7.2	1.5
Recognizing people	45.2	25.1	19.3	8.9	1.5
Reading words on screen	23.2	24.6	27.7	21.5	3.0
Reading					
Headlines	61.1	14.9	10.7	9.6	3.7
Large print	64.1	13.1	8.7	4.3	9.8
Standard text	29.1	26.3	20.7	18.6	5.3
Telephone books	16.0	24.5	20.9	32.9	5.6
Driving					
Short distances daytime	41.5	13.1	7.9	3.0	34.5
Long distances daytime	24.6	16.7	10.2	5.4	43.0
Short distances at night	11.4	15.0	10.9	15.6	47.1
Long distances at night	5.7	9.0	10.9	18.5	55.8

As with our analysis for symptoms, we looked across all measures of functional impairment to see the highest level reported by patients in any of the 12 measures. Table 7 presents these results.

Table 7: Highest Level of Presurgery Visual Impairment Reported by Patients for Any of Twelve Functional Activities[a]

	Amount of difficulty			
	None	Little	Moderate	Severe
Greatest difficulty reported for any of 12 functions	6.0%	18.0%	25.4%	50.5%
Greatest difficulty reported for any of 10 functions[b]	9.7	22.3	29.0	39.1

[a]The 12 activities are listed in table 1.

[b]Excludes driving long distances at night and reading telephone books.

As can be seen from table 7, 6 percent of patients reported having no functional impairment prior to their cataract operations. Importantly, if these patients in fact did not have any limitations in their daily living resulting from their cataracts, then they did not meet an essential criterion in both the AAO and AHCPR guidelines on when surgery is appropriate. Further, if one expands the category of "questionable" surgeries to include those on patients who report having only "slight impairment," then 24 percent of the surgeries covered by our sample fall into this category.

CONCLUSIONS AND IMPLICATIONS

What, then, do all these numbers I have presented mean? Are things going well with cataract surgery, or is there reason for concern? At the most general level, it seems that the news reported by patients is both good and bad. On the positive side, it seems clear that few patients (between 4 and 5 percent) experience uniformly negative changes with either symptoms or functions and even fewer (about 2 percent) experience uniformly negative outcomes for both symptoms and functions taken together. In addition, the majority of patients (approximately two out of three) report improvements in both symptoms and functions after their operations.

However, it is clear that some patients do report negative outcomes, which means that efforts at monitoring quality of care in this area remain important. As I mentioned, the data from cataract surgery patients is only one component of a larger study of quality assurance under the Medicare program. Our report from the full project, due this summer, will address the needs for quality assurance in greater detail.

The most important immediate message from our data, however, regards medical necessity. Although inappropriateness has not been clearly defined, our survey results show different amounts of questionable surgery based on different criteria for appropriateness.

If we adopt the criterion that any level of problem with either symptoms or functions (even those the patient considers slight) is sufficient to warrant surgery, our study shows that very few surgeries (2.5 percent) were inappropriate. But if the criterion we choose is functional impairment--the one adopted by both the AAO and AHCPR guidelines--then 6 percent of surgeries in our study were inappropriate. (This is based on the proportion of patients who indicated they had no limitations in any of the 12 functional activities included in our survey before their cataract surgeries.)

If we escalate the criterion for inappropriateness from "no problem" to "slight problem," then 16 percent of our respondents' surgeries were questionable. (This corresponds to the proportion of patients who indicated they had no more than "slight" problems with either symptoms or functions prior to surgery.)

Finally, if the criterion is one of substantial functional impairment, almost a quarter of our respondents (24 percent) would have had inappropriate surgery, reporting to us that they had no more than slight problems with visual function before their surgeries.

Because of the magnitude of total Medicare expenditures for cataract surgery, even small changes in the rate of inappropriate surgery could have notable financial implications. Exactly how much money would be "saved" on a continuing basis by reducing inappropriate cataract surgeries is difficult to estimate. That figure would require, at a minimum, knowledge of how many cataracts would later progress to a point at which they did cause functional impairment (and when that occurred), trends in the incidence of cataracts in coming years, and changes in the costs of the procedure. However, to provide a sense of how much was spent in a recent year on potentially inappropriate surgery for cataracts, we did the following:

-- we hypothesized that the data from the four states were not unrepresentative of current practice in the nation as a whole,

-- we applied the permissive criterion that for the surgery to be considered inappropriate, a patient must have reported no functional impairment, and

-- we calculated that every 1 percent of cataract surgeries represented approximately $34 million in expenditures for the Medicare program as a whole.[1]

In this scenario, given 6 percent of patients who experienced no functional impairment, Medicare would have spent approximately $200 million in 1991 for inappropriate cataract surgery.

The actual expenditure on unnecessary cataract surgery in 1991 is thus uncertain, as is the true long-range savings that could be obtained through a decline in inappropriate cataract surgery over time. Our findings, however, are provocative in that they describe a policy situation in which expenditure reduction enhances the quality of care. In effect, if the volume of inappropriate surgeries could be reduced, not only might financial savings be realized but health services to individuals with cataracts would improve. At a time when health care reform is often viewed as a "zero sum game" (where all situations have both winners and losers), the situation with cataract surgery is one in which mechanisms for reducing inappropriate care improve both the health of patients and that of the health care system.

This concludes my statement today. I would be happy to answer any questions you may have.

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[1]Medicare expenditures for cataract surgery in 1991 were estimated to total $3.4 billion. Denis M. O'Day et al., Cataract in Adults: Management of Functional Impairment (Rockville, Md.: U.S. Department of Health and Human Services, Agency for Health Care Policy and Research, February 1993), p. 21.

METHODOLOGY

The questionnaire used to collect the information presented in this testimony was developed over the course of the initial phases of this project. Discussions were held with cataract patients, clinicians who deal with cataracts, and experts in the measurement of clinical outcomes to ensure that the instrument provided both valid and reliable responses. Once the questionnaire was completed, it was pretested on a random sample of 144 cataract patients.

The survey was sent to a random sample of patients in California, Massachusetts, Pennsylvania, and Texas. The focus on states to define the sampling frame was necessary because quality assurance under the Medicare program is a state-based activity. We intentionally picked four relatively large states, so that we could be assured of having a reasonably large number of patients in the study.

The questionnaire had four main sections. One asked for general information about the patients (age, gender, and so on). The three other sections focused specifically on items related to the basis for, and outcomes of, cataract surgery. The first of these sections asked patients to describe the nature and extent of the symptoms and functional impairment they were experiencing prior to their surgery. Specifically with respect to symptoms, we asked the patients whether they had experienced any of the following 6 symptoms in the 4 weeks prior to their surgery and, if so, how much they were bothered by them on a scale ranging from not at all to severely:

-- fuzzy, blurred, or clouded vision;

-- vision restricted by glare or excessive sensitivity to light;

-- double vision;

-- itching or burning in the eye;

-- floaters (small visual obstructions);

-- a feeling of something in the eye.

With respect to functional impairment, the questionnaire asked the extent to which the patients' daily lives were affected by limited vision. The survey assessed visual functioning through a set of questions that asked respondents to describe their difficulty prior to surgery in watching television, reading, and driving. Respondents could choose among four levels of difficulty: no, little, moderate, and great, plus a "not applicable" category for those who did not engage in the specified activity.

The third section of the survey instrument asked about short-term outcomes. Examples of short-term outcomes include pain, swelling, and infection. These are discussed more fully in our report and I will not present any findings in this statement regarding them.

The final section of the instrument was concerned with long-term outcomes. As with our questions on the condition of the patient prior to surgery, this section also focused on how symptoms and functions changed after the surgery and, in fact, employed the same 6 symptoms and 3 dimensions of function. Our interest in questions on long-term outcomes was to see whether, and the extent to which, patients improved along all items.

The emphasis placed in the AAO guidelines on the significance of visual functional impairment as perceived by the patient underscores the particular relevance of patient-reported data when assessing the appropriateness of cataract surgery. However, there may still be concerns about the accuracy with which patients would recall, after the surgery, what their perceived limitations were before it took place. While memory

can certainly fade over time, we concluded that the data we collected, almost all of which were gathered in a 5-to-10-month window after surgery (median 7.3 months), provided strong evidence of actual patient perceptions for the following reasons:

-- how well one sees after a cataract operation, compared to before it was performed, is a highly salient question to anyone who has undergone the procedure;

-- the type of information we requested concerned patient experiences directly over an extended period of time;

-- there is no stigma attached to the information we sought and therefore more or less unconscious distortion may not be as likely as with more sensitive topics;

-- the slowness with which cataracts often develop means that patients' assessments of their own visual impairments prior to the surgery may be better grounded **after** the surgery than before it. It is only after the cataract has been removed and recovery from the surgery is largely complete that the patient can experience what he or she had been missing visually beforehand. This expectation was borne out in a small-scale pilot test that we conducted, in which we compared patient reports from before cataract surgery with the recollection of those same patients several months after surgery.

Therefore, we concluded that the use of patient assessments of presurgical visual impairments collected after the surgery has occurred is not only legitimate but preferred, to improve accuracy, despite the somewhat greater risk of blurred recall.

Ms. SMITH. The next speaker is Dr. Denis O'Day, Professor and Chairman, Department of Ophthalmology, Vanderbilt University.

Dr. O'Day chaired the Committee under the Agency for Health Policy and Research that developed the recently released guidelines on cataract surgery and will talk to the basis of those guidelines as well as the role of patient perception and treatment decisions.

Dr. O'Day.

Excuse me. Senator Burns, did you want to say a few words?

STATEMENT OF SENATOR CONRAD BURNS

Senator BURNS. Yes, I would and then I'll just put my statement in the record.

I had mine done in December and no matter what these folks over here at GAO or anybody else says, it's worth the money. I don't know what it's done to my golf game yet, but I'll tell you what, whenever you go out in the bright sunlight and a cateract in this eye, you look like you're looking on the inside of a milk bottle, you have no depth perception or anything like that, I think it's about time you start taking corrective surgery for it.

My doctor also told me, Dr. Good in Billings, Montana, who is an expert in his field, "Don't do it until I take a look at it." So I put up with that for about 3 or 4 years when I thought it really got to the extremes.

I want to thank the GAO and of course the Committee on Aging for getting after this a little bit. I want to just make some comments though. Some would say this surgery would not be worth the money; I happen to be on the other side of the aisle. My father had two cataracts taken off and he died in December of this year at the age of 86. I don't think dad would have driven an automobile and in fact, the first time he was ever in a hospital was in December and that's when we lost him, in his whole life. Of course with cataract surgery, it is not a simple operation but it is an outpatient operation. To my father it was a godsend because I don't think dad could have operated the automobile, and there's a lot of things he could not have done and enjoyed any kind of quality of life in his later years.

I do want to register a complaint though this morning. We tried to get copies of this report. I would like to have gone through this report before this hearing this morning so that we might have offered some comments because I, for one, am not one to take the GAO as the living last word in this body, although they do great work. We couldn't get the report and I probably will save some of my comments for that, and for the life of me, I have not come up with a real good reason why. We would like to see it and go through it and make our own assumptions, if we could, based on the information that they have.

With that, I would just leave my comments. If you have a record, I will leave my comments with that.

I can tell you this is the reason we work, this is the reason we try to do everything—to improve our quality of life. For surgery such as this, especially affecting eyesight which is one of our greatest senses, adds so much to our quality of life all through our adult years and into our later years.

With that, I would just like to make that statement. I'm looking forward to finally getting the report and after we get to see it, then we can probably comment on it, if you don't mind.

Thank you very much.

[The prepared statement of Senator Burns follows:]

PREPARED STATEMENT OF SENATOR CONRAD BURNS

Before Senator Heinz died, he requested the GAO report on medically unnecessary procedures, similar to that done by the Department of Health and Human Services for Medicare. How the focus shifted to cataract surgeries, I still don't know.

There are other things I don't know, answers I would like to have. Not having the advantage of seeing the report ahead of time, it was difficult to formulate questions. I must say, it was very frustrating not having access to these findings. I understand that policy dictates the report be shared first with the Member who requested the report, but given the fact that this Member is no longer with us, not being willing to share it with the Committee on which he sat seems to be, at the very least, a breach of the GAO's charter to serve Congress.

My staff tried on a number of occasions to obtain, if not the report draft then, a summary of the report findings. The lack of responsiveness is inexcusable. I understand that considerable concern has been expressed about this report, though nobody actually knew what the report would say, until today, and there was fear of leaking the findings to interested parties. That is understandable. However, as a member of this committee, I would hope that this information would be made available, especially after direct requests were made. The fact that my requests were denied leaves me with serious doubts about the service of the GAO.

That aside, I would like to make just a few remarks and reiterate some concerns I had, many of which were raised in the workshop.

I developed a cataract a number of years ago and just recently had surgery to remove the cataract. The surgery was simple—done on an outpatient basis and the results are nothing short of miraculous. I don't know if anyone here has experienced what it is like to have impaired vision, but for me it was like looking through a milk bottle and it is very debilitating.

But every individual has a lifestyle that dictates whether or not that vision is important to them. For a clock repairman, clear vision is essential. For a retired women who only wants to enjoy her garden, she may not feel surgery is necessary until she can no longer distinguish the colors. What I am saying is the patient is the one who determines whether or not the procedure is necessary.

I have now had a chance to review the GAO Report on Cataract Surgery and the comments made by our panelists. I find a number of things to be disturbing. To begin with, the survey was conducted in only four states, and yet the results are perceived to be nationwide.

The survey, even as admitted by Ms. Chelimsky, failed to question the patients prior to surgery when symptoms and functional impairments were fresh in their mind. By waiting 4–10 months following surgery to question these patients, one risks having no basis on which to compare. A survey such as this one also fails to take into account the patient's expectations. If a patient approached surgery expecting to be able to read without glasses or do fine needlework, when they were not able to do that for years before the cataract developed, their expectations may not have been met, and they may see the surgery as less than successful.

Most of all however, is the lack of a definition for "inappropriate." The survey summary states that, because there is no definition, "the survey results show different amounts of questionable surgery based on different criteria for appropriateness." I find this to be irresponsible reporting. When a survey takes fives years to conduct and the results show that anywhere from 2.5% to 24% of cataract surgeries are unnecessary or inappropriate, that says to me the survey has not been professionally conducted. It certainly does not make this report newsworthy or even suitable for distribution. If a report was required to be issued, it should have said the findings were inconclusive. I certainly hope that the subsequent report on quality assurance will prove to be more substantial.

The Inspector General's Report on the same subject in 1991 (dealing primarily with Medicare) found that only 1.7% of the cataract surgeries reviewed were determined to be medically unnecessary. Of course any surgery performed unnecessarily is something that needs review. I was concerned to hear Ms. Chelimsky say that all these reports have flaws, and therefore, what we need to do is do them anyway and compare results. Once again, I think this is irresponsible reporting. To say that

the data in this report shows that opportunities exist to reduce the costs of health care and improve the quality is a great overstatement.

I think it is important to look at the incidence of medically unnecessary procedures. It is clear that these do occur, in every area of health care. However, to do this, one must first spell out definitions. Once this is done, we may be well on our way to discovering outcomes and deciding what procedures truly benefit the patient. I look forward to this happening and would encourage the GAO, AHCPR, research hospitals, and interested medical specialty groups to work together to determine exactly what is meant by medically unnecessary, how we should go about reducing this instance, and how we can ensure safe, successful and high quality health care.

Ms. SMITH. In fact, Senator, the hearing record will be open for up to 10 days and anyone is invited to submit questions or comments for the record.

Dr. O'Day.

STATEMENT OF DENIS O'DAY, M.D., PROFESSOR AND CHAIRMAN, DEPARTMENT OF OPHTHALMOLOGY, VANDERBILT UNIVERSITY

Dr. O'DAY. Good morning.

Thank you, Nancy. I appreciate the opportunity to be here.

In the next few minutes, I want to discuss four issues that relate to cataracts. First is what is a cataract? Second is, how does a cataract affect us? Third, how is it treated? Finally, how does the guideline panel recommend the decision be made regarding surgery?

First of all, what is a cataract? A cataract is a clouding of the lens of the eye. It's something that occurs as we all get older. Each year, approximately 400,000 Americans will develop a cataract. It's so common as to be almost a natural event. It's an inevitable consequence of aging in most of us.

What is important to remember is that a cataract does not normally threaten the health of the eye. It affects vision but it doesn't normally affect the health of the eye except in rare circumstances.

How does the cataract affect us? I think it's obvious that vision is one of our most precious senses. There is a direct link between good vision and quality of life. When our vision starts to fail, or something starts to happen to our vision, our sense of independence is threatened, our livelihoods are threatened, we tend to become isolated and fear starts to intrude into our lives. Those are very powerful changes that come when something starts to happen to our vision.

So although a cataract directly affects vision, the real point about a cataract is that it begins to affect the quality of our lives. That's a very important understanding we must have. We must understand also that the impact of our vision is highly individualistic and it depends on who we are and what we do, and what we desire to do.

How is a cataract treated? One of the great success stories I think in the last two decades has been cataract surgery, the evolution of a procedure that is highly successful and has the capacity to really restore vision and therefore, to restore independence. It's something I think that American medicine can justly be proud of because this is the country that really made it happen.

It's also important to remember that most patients who have cataract surgery can expect an excellent outcome. It's also important to note that complications occur. Those complications can lead to

functional impairment so that even though complications are not common, they can be devastating to the individual.

It is important to remember that although cataract surgery is performed very frequently in the United States, that does not equate with a minor surgical procedure. A minor surgical procedure, I might state, is something that is done on somebody else. So there are risks as well as benefits and it's important to remember that.

How is the decision for surgery made? There are three elements to that, according to the guideline. One is an eye examination that confirms that a cataract is present and appears to be the cause for the decrease in vision. The second element is a discussion between the ophthalmologist who might perform the surgery, if the patient needs it, and the patient about the risks and the benefits of surgery. The third and perhaps the most important one is an exploration of the impact of the visual symptoms on the patient's life, the discussion that goes on between the patient and the physician so that the patient is then in the position to be able to make a decision about whether the symptoms and the functional impairment they have is severe enough to warrant going through the risks and inconveniences of surgery. Those are the three elements that have to be present.

The important point is the final decision rests with the informed patient. We believe that is the very safest place for that decision to be placed.

Out of this arises a key question. What is functional impairment? That's a value judgment. I would submit to you that there are three elements to that decision. One is the culture we live in; the second is the cultural expectations that our society has; and the third is the individual's expectations, fears, hopes, and desires about their life.

An example of the culture we live in is the fact we are a society that virtually doesn't have a mass transportation system. That places an imperative on driving if we are going to survive independently in our later years. For a person who doesn't need to drive, there are different cultural expectations, but I think you can see that the decision is a complex one involving many considerations.

The important point is that there is an element of fear that the physician that sits with the patient has to be able to deal with and physicians—ophthalmologists are physicians first—are trained first as physicians so they can recognize that cataract is not just an eyeball disease. Cataract is a disease that affects the whole person, their integrity and their independence as they age. That is a very important concept.

Finally, is there a way that we can make a judgment that is more objective than this subjective approach? For this people look to tests. If you're going to have a test, you want the test to be valid. The test has to identify all the people who need the procedure and who will do well with it and not identify folks who don't need it or who might do poorly. That's a very stringent, scientific requirement.

There are two types of tests. One is a device that seeks to measure functional impairment, some sort of instrument or testing ma-

chine, or something like that. Another test is a questionnaire such as the one you've just heard described that seeks to ferret out and capture symptoms of functional impairment.

There are two requirements for these tests. One is the scientific validity of the test. We have to be sure if we're going to use a test that it has scientific validity. Once that is so, then we have to make a judgment about where we are going to set the scale. That's a value judgment and we can't get away from the fact that it's a value judgment in which many, many considerations come into play which are societal as well as personal.

To give you an example—one that perhaps is remote from this issue, consider the college admission test which is given to students to see whether or not they can go to college. The first part is the measurement of students' aptitudes. The testing societies make as good an effort as they can to make sure they are really measuring what they think they are measuring, but as all of us know, it doesn't always work. You get a number out of the test and that number says something about whether you're going to go to college.

College A says, well, if you get a score of 19, you'll make it through college. Another college says no, you've got to make 27. That's a value judgment, and these are value judgments that you've heard discussed this morning about what constitutes a need for surgery. They should not be treated lightly because they have enormous societal implications.

I think the conclusion that I would bring to you is that the guideline looked at these issues very carefully, recognized that the science is lacking currently in objectifying the patient's decision-making process for surgery. Recognizing that point, the guideline recommends that we as physicians turn to the patients and seek from them a true feeling of where they are in their lives, what impact the cataract is having on them and whether or not the cataract surgery will truly help them. Patients informed about the issues are able to make a decision and we believe that is the safest place to have it made.

That concludes my remarks. Thank you.

[The prepared statement of Dr. O'Day follows:]

STATEMENT FOR SENATE HEARING
DENIS M. O'DAY, M.D., F.A.C.S.
April 21, 1993

The ability to see is one of our most precious senses. Good vision can make the difference in walking, driving safely, reading, watching TV, and enjoying being with family and friends. There is a direct link between good vision and independence and quality of life.

When our vision begins to fail, fear of blindness can become a powerful force in our lives. Independence and livelihood are threatened. Isolation can become a reality. Cataract is one of the most significant causes for decreased vision, especially as we grow older.

A cataract is a naturally occurring cloudiness in the lens of the eye. Each year, approximately 400,000 Americans, mostly elderly people, develop cataracts. The decrease in visual function that can occur with cataract can lead to a diminished or lost ability to do many things: everyday activities, to participate in hobbies and other leisure activities, to work in one's occupation. The guideline we have developed speaks from the patient's perspective on these issues. We looked at the visual and functional problems due to cataract and how the disease should be managed so that the best possible outcome is assured for the patient.

The care of a patient with cataract is multi-dimensional. Effective care involves not just ophthalmologists and optometrists. But effective care also involves many other physicians and health care providers. The multi-disciplinary panel appointed by AHCPR to prepare this guideline reflects this broad participation. The approach taken by the panel was comprehensive. Over ninety separate topics concerned with cataract were extensively researched in the literature. These addressed issues of concern to the cataract patient from when the visual problem is recognized to the completion of treatment. Nearly 8,000 pieces of literature were carefully reviewed. As a result, we now have for the first time a comprehensive understanding of the state of our knowledge for cataract.

An important question from the perspective of the patient is - when should the cataract be removed? Cataract surgery is never justified solely because a cataract is present. Cataracts form naturally in every one of us as we age. But for many of us, functional impairment is absent or so minor that we will neither desire nor need cataract surgery. The appropriateness of cataract surgery depends upon the extent to which visual loss as a result of the cataract interferes with our everyday activities.

How can this be judged?

First, it is necessary to be sure by careful examination that the cataract is the cause of the visual impairment. We want to be sure that some other disease is not causing the symptoms. Next, the patient in discussion with the surgeon needs to assess the degree of functional impairment. The patient's own subjective assessment of his or her vision combined with lifestyle needs should be the only determination of whether or not surgery takes place. Ultimately, and this important, the decision resides with the patient. Currently there are no objective stand alone measures of functional impairment that can serve as precise indications for surgery. This guideline panel believes that the development of such measures is of high priority.

Cataract surgery is a highly successful procedure. The vast majority of patients can expect a satisfactory outcome. However, complications do occur and when they do there may be further visual loss with further functional impairment. For this reason, how care is rendered in the post-operative period is extremely important to the outcome. The ophthalmologist who performs the surgery also has the responsibility and ethical obligation for care following surgery. This guideline offers clearly defined roles for responsibility for health care professionals who participate in the post-operative care of cataract patients.

April 15, 1993

The effect that visual loss due to cataract can have on our lives makes this guideline an important document. How those of us who have visual loss due to cataract, and those of us who will develop it in the future are to be cared for should be of vital concern. This guideline defines the appropriate care for patients with cataract. We want patients to know exactly what to expect when they go into a doctor's office with a cataract. And we want doctors and everyone else involved on the treatment team to know what is expected of them. With this guideline, those who need the surgery will receive it with the best possible outcome.

Thank you.

April 15, 1993

Ms. SMITH. Thank you.

Our next speaker is Dr. Risa Lavizzo-Mourey, Deputy Administrator, Agency for Health Care Policy and Research. She is a geriatrician and she will discuss the process of guideline development for cataract surgery as well as the importance of patient involvement in treatment decisions.

STATEMENT OF RISA LAVIZZO-MOUREY, M.D., DEPUTY ADMINISTRATOR, AGENCY FOR HEALTH CARE POLICY AND RESEARCH, HHS

Dr. LAVIZZO-MOUREY. Good morning.

As a geriatrician and the Deputy Administrator of AHCPR, the Agency for Health Care Policy and Research, I'm pleased to be here this morning to talk about the report and our guideline process. I've prepared some statements that will be in the record and I'm going to just highlight some remarks from that statement.

For those of you who may not be familiar with AHCPR, we were formed in 1989 as a component of the Public Health Service for the purpose of improving the quality, appropriateness and effectiveness of health care. We do this through two major programs, both scientifically based—one that studies the research on cost, quality and access and another, the Medical Effectiveness Treatment Program (MEDTEP), that is directed at improving the clinical practice of care. It's this latter activity that facilitates the development of clinical practice guidelines.

Let me tell you a little bit more about this process. To develop clinical practice guidelines, AHCPR sponsors panels of private sector experts or contracts with public or private, nonprofit associations. The guidelines are developed under our sponsorship. They are systematic statements that are science-based and are a comprehensive review of the science literature.

They tend to recommend the most effective ways of diagnosing, treating or preventing specific health problems and reflect the best judgment of an interdisciplinary group of health practitioners, experts, and of course, consumers.

AHCPR had several reasons for undertaking a guideline on cataracts in adults a few years ago. They include, first, the high prevalence of cataract disease in the elderly. As a geriatrician, I can tell you that over 50 percent of elderly persons between the ages of 65 and 74 have cataracts. If you look at patients that are over 75, this percentage increases to 70 percent. So it's a common problem and it's a problem that is going to increase as our population ages.

Second, cataracts have a potential impact on the independence and quality of life for elderly persons who have functional impairment due to this disease.

Third, cataracts represent a high volume of surgery. In 1991, as we've heard, over 1.35 million cataract surgeries were done in the United States on the Medicare population at a cost of approximately $3.4 billion.

Fourth, there seems to be a variation in the practice patterns of cataracts. As you look across cities, there is a three- to four-fold difference in the rate of cataract extraction.

So for these reasons, we were very pleased that Dr. O'Day chaired an 18-member panel of non-Federal experts to develop the

cataract guideline. This panel was comprised of seven ophthalmologists, two optometrists, an anesthesiologist, two primary care physicians, a psychiatrist, three nurses, a social worker, and of course, a consumer representative. The multidisciplinary approach that I've described is a distinctive feature of AHCPR guidelines and one we feel improves the comprehensiveness and broad base of the scope.

In the process of developing this guideline, the panel reviewed nearly 8,000 pieces of scientific literature that were published in peer-reviewed journals. One can easily conclude from this that the science underlying the management of cataract disease is moving very quickly and that it is difficult for even the most diligent clinicians to carefully review all of these articles.

The panel then considered the health policy issues affecting cataracts, such as health care resources, patient and practitioner concerns, ethical questions and legal questions. Then through open meetings which were widely advertised to enhance participation from outside groups, the panel received oral and written testimony.

The results of both this testimony and the literature review were then incorporated into a draft guideline that was reviewed by clinicians and other health care professionals throughout the Nation who had been chosen because of the fact that the guideline was likely to impact their practice of care or their decisionmaking. The final guideline combines the panel's original draft and comments from the reviewers.

Let me just highlight several important points that were contained in the guideline. First, there is no fixed threshold which dictates the removal of a cataract. Second, cataract surgery is almost never justified solely because a cataract is present. Often a cataract does not cause sufficient diminution and function to warrant surgery. Third, a patient's own assessment—this is the point that Dr. O'Day emphasized—a visual assessment, and patient's preferences with respect to surgery should be the factors of paramount importance in deciding whether to opt for surgery.

There are, of course, other options to surgery, including watchful waiting and corrective lenses. Delay in surgical removal of a cataract does not jeopardize the outcome of surgery and therefore, the patient and the physician should work as partners in the decisionmaking process, but the final determination rests with the patient.

The release of the guideline shows how AHCPR's programs can work together in tandem and enhance one another. The guideline process and the Medical Effectiveness Treatment Research Program worked together in this effort and complement one another. Dr. Steinberg and his colleagues head largest research efforts related to adult cataract disease and they worked very closely with the guideline panel to determine the methodologies used in reviewing these 8,000 pieces of literature and in informing the panel on methodologic issues.

We are pleased with the favorable review that the guideline has received from professional organizations within the health care community. A number of groups have given formal endorsements, including the Alliance for Aging Research, the Academy of American Ophthalmology, the American College of Surgeons, the American Society of Ophthalmic Registered Nurses, the Association of

University Professors of Ophthalmology, the National Society to Prevent Blindness, and the American Nurses Association.

Let me tell you a little bit about how we disseminate this information. All AHCPR guidelines are designed to present information in an understandable way to the practitioner who may be practicing in a variety of settings. A consumer version of each guideline is also published, both in English and in Spanish. For the cataract guideline, we took an intensive effort to make consumers and health care practitioners aware of the availability of the guideline and related patient information.

As of early April, AHCPR had received 8,200 requests for the cataract guideline or its accompanying booklet for patients and approximately 65 percent of these requests were from patients. AHCPR maintains a clearinghouse through which consumers can order copies and we have a toll-free 800 number to facilitate this.

AHCPR plans to continue its involvement in the appropriate clinical management of cataracts in several ways. First, we will support a new expert panel to update the cataract guideline to reflect cutting edge, scientific advances in medical technology. We will also carefully monitor the implementation of the guideline and finally, we will begin evaluating the cataract guideline this summer in a variety of ways.

A key issue that we've already spoken about that was raised by the guideline is the lack of objective, stand alone measures of functional impairment that can serve as precise indicators for surgery. AHCPR is addressing this issue, we are increasing our support of research to improve the methodologies and measurement systems needed for functional assessment, and have awarded a grant to measure the activities of daily living, particularly related to vision and to assess these new scales for assessing functional status related to cataracts.

In conclusion, although AHCPR's cataract guideline did not address the level of inappropriate cataract surgery, its recommendations complement the conclusions reached by the General Accounting Office in their review of cataract surgery. Both studies share important recommendations.

First, the patient should be well-informed and active participant in clinical decisionmaking. In addition, the appropriateness of cataract surgery is dependent on the extent of functional impairment. Finally—again, we emphasize this point several times, but it is probably one of the most important ones that we would like to make today—the ultimate decision whether or not to have surgery rests with the patient.

That concludes my remarks. I'd be happy to answer questions later on the guideline or our research.

Thank you.

[The prepared statement of Dr. Lavizzo-Mourey follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Agency for Health Care Policy
and Research
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STATEMENT

of

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U.S. Public health Service
Department of Health and Human Services

Good morning. I am Dr. Risa Lavizzo-Mourey, a geriatrician and Deputy Administrator of the Agency for Health Care Policy and Research or AHCPR. I am pleased to be here this morning with Drs. Denis O'Day and Earl Steinberg to discuss the AHCPR-sponsored clinical practice guideline on the management of functional impairment due to cataract in the adult.

For those of you who may not be familiar with the organization, AHCPR was established in 1989 as a component of the U.S. Public Health Service. Its purpose is to improve the quality, appropriateness, and effectiveness of health care, and to improve access to health care services. We carry out these responsibilities by conducting and supporting two primary programs: research and analysis of health care costs, quality, and access; and, the medical treatment effectiveness program, directed at improving the practice of clinical medicine. This latter activity includes facilitating the development of clinical practice guidelines.

CLINICAL PRACTICE GUIDELINES

To develop practice guidelines, AHCPR sponsors panels of private sector experts or contracts with public or nonprofit private organizations. Guidelines developed under AHCPR sponsorship are systematically developed statements that are based on a comprehensive review of scientific literature and

recommend the most effective ways of diagnosing, treating, or preventing a specific health problem. They reflect the best judgment of an interdisciplinary group of recognized expert health care practitioners and consumers who base their decisions on a rigorous examination and statistical synthesis of available scientific literature.

On February 25, 1993, AHCPR released *Cataract in Adults: Management of Functional Impairment*, its fourth clinical practice guideline. Other AHCPR-supported guidelines that have been released include *Acute Pain Management: Operative or Medical Procedures and Trauma; Urinary Incontinence in Adults; Prediction, Prevention, and Early Intervention of Pressure Ulcers*; and, *Depression in Primary Care: Detection, Diagnosis, and Treatment*. By the end of FY 1993, a total of 13 guidelines will be available to the public and 11 other topics will be under development.

AHCPR had several reasons for developing a practice guideline on cataract in adults:

- The high prevalence of cataract in the elderly U.S. population. About 50 percent of persons age 65 to 74 have cataract. The prevalence increases to 70 percent for those 75 and older. This problem will grow in importance as America's aging population grows.

- Decreased independence and quality of life for people whose cataracts cause functional impairment.

- The high volume of cataract surgery. In 1991, an estimated 1.35 million cataract surgeries were reimbursed under Medicare in the United States. These were accomplished at a cost to Medicare of approximately $3.4 billion.

- Wide variation in cataract care practice. As an example, Medicare data reveal a three-fold difference in rates of cataract extraction in cities across the United States.

Dr. O'Day chaired the 18-member panel of non-Federal experts that developed the cataract guideline. It was comprised of seven ophthalmologists; two optometrists; an anesthesiologist; two primary care physicians; a psychiatrist; three nurses; a social worker; and a consumer representative. This multidisciplinary approach is a distinctive feature of AHCPR's guideline development process in that it helps ensure that guidelines are comprehensive in scope, rather than narrow--as often happens when only one specialty is involved.

In the process of developing the cataract guideline, the expert panel reviewed nearly 8,000 pieces of published, peer-reviewed scientific literature. Treatment of cataract is a field marked by rapid change and no individual practitioner--however diligent--could scientifically sift through this vast amount of literature on a regular basis.

The panel then considered health policy issues, such as health care resources, patients' and practitioners' concerns, and ethical and legal questions. Through two open meetings, which were widely advertised to enhance attendance, the panel received oral and written testimony from additional groups and individuals.

The results of both the literature review and the open meetings were incorporated in a draft guideline. A group of clinicians and other health professionals carefully chosen on behalf of the users who would benefit from the guideline evaluated the draft for its validity, efficacy, and applicability in practice settings. The final guideline combines the panel's original draft with the comments of reviewers representing professionals and patients around the country.

I would like to highlight several important points contained in the guideline:

- There is no fixed, absolute threshold in time which dictates removal of a cataract.

- Cataract surgery is almost never justified solely because cataract is present. Often the cataract does not cause sufficient diminution in function or quality of life to warrant surgery.

- The patient's own assessment of visual impairment, and the patient's preference with respect to surgery, should be factors of paramount importance in deciding whether to opt for surgery.

- Other options are possible, including "watchful waiting."

- Delay in surgical removal of a cataract does not jeopardize the outcome of surgery.

- Physician and patient should work as partners in the decisionmaking process. But the final determination is the patient's.

The guideline also emphasizes the importance of post-operative care to cataract surgery outcome. It places responsibility for follow-up care on the operating surgeon and recommends defined roles and responsibilities for ophthalmologists, optometrists and other members of a team of appropriately trained professionals, including community health nurses and social workers.

Release of the cataract guideline shows how two of AHCPR's science-based programs--development of practice guidelines and medical effectiveness research--work in tandem, each reinforcing the other. Dr. Steinberg directs the AHCPR-funded cataract Patient Outcome Research Team or PORT. This study is one of the largest, most comprehensive cataract research studies ever conducted in the United States. Dr. Steinberg and his colleagues contributed a great deal to the methodology used to organize the extensive literature searches that are the basis for the cataract guideline recommendations. As I noted earlier, the guideline development panel examined nearly 8,000 pieces of scientific literature.

Dr. Steinberg and his team of researchers are examining variations in cataract management, and the short-and long-term outcomes and costs associated with cataract. Findings published by the PORT on the incidence of retinal detachment after use of YAG-laser capsulotomy--a procedure commonly used to correct opaqueness of the remaining lens capsule after cataract extraction--showed that the procedure is associated with a nearly four-fold increase in the risk of retinal detachment. In 1991, 640,000 YAG-laser capsulotomies were performed on Medicare patients. This finding was included in the cataract guideline.

We are pleased with the favorable review the guideline has received from professional organizations within the health care community. Groups that have given formal endorsement to the guideline include: the Alliance for Aging Research; American Academy of Ophthalmology; American College of Surgeons; American Society of Ophthalmic Registered Nurses; Association of University Professors of Ophthalmology; National Society to Prevent Blindness; and the American Nurses Association.

DISSEMINATION OF PRACTICE GUIDELINES

All AHCPR-supported guidelines are designed to present information in understandable terms to the practitioner, in any setting or location. A consumer version of each guideline also is published in both English and Spanish. For the cataract guideline, we undertook an intensive effort to make consumers and health care practitioners aware of the availability of the guideline and related patient information. As of early April, AHCPR has received 8,200 requests for the cataract guideline and/or the patient booklet. Approximately 65 percent of the requests have come from consumers and 35 percent from professionals.

AHCPR held a press conference to announce the release of the guideline. The conference was covered by CNN, CBS, NBC, the Washington Post, New York Times and other major media. We worked with the American Association of Retired Persons to produce a video news release on cataract care and we produced and sent an audio news release to 200 radio stations. In addition, we mailed the patient guide and information on the guideline to nearly 40 senior citizen and consumer-oriented national organizations, and to approximately 800 consumer media. Furthermore, AHCPR sent the cataract guideline to over 100 national, state, and local medical newsletter and journal editors and to nursing and hospital press. AHCPR also has a publications clearinghouse through which consumers can order copies of AHCPR publications by calling a toll-free number (1-800-358-9295).

ROLE OF THE PATIENT IN CLINICAL DECISIONMAKING

We believe that with widespread acceptance and use of the cataract guideline, patients will become better informed health care consumers who work as partners with their health care providers. This could lead to a reduction in inappropriate and ineffective health care practices, improvement in the quality of health care, and a decrease in overall health care costs. These objectives are key components of many of the health care reform proposals now under consideration by policymakers. Many reform proposals recognize the importance of providing more information to consumers, either through clinical practice guidelines or other mechanisms, as a way of reducing unnecessary medical services and improving the quality of health care.

In addition to the development and dissemination of clinical practice guidelines, AHCPR supports research directly related to increasing patient awareness and active participation in treatment decisions. For example, AHCPR is funding investigators at Harvard University to do a multi-site evaluation of an interactive video disc or IVD on benign prostatic hyperplasia produced by the Foundation for Informed Medical Decision Making. AHCPR has under review proposals to evaluate other IVD's on surgery for low back pain, breast cancer treatment, and ischemic heart disease. All of these projects are aimed at improving health care decisionmaking through developing a better informed and shared decision process between patients and their physicians.

SUMMARY

AHCPR will continue to be involved in the assessments of appropriate clinical management of cataract in the adult in several ways. First, we will support a new expert panel to update the cataract guideline to reflect new scientific knowledge and advances in medical technology. We also will carefully monitor the implementation of the guideline. Finally, we plan to begin evaluating the cataract guideline in a variety of care settings this summer.

A key issue raised in the cataract guideline is the lack of objective, stand-alone measures of functional impairment that can serve as precise indicators for surgery. AHCPR is addressing this issue. We are increasing our support of research to improve the methodologies and measurement systems needed for functional assessments. For example, an AHCPR grantee has developed a measure (the Activities of Daily Vision Scale) for the assessment of visual loss in persons with cataract. This work is essential if we are to change practice patterns and improve the quality of cataract treatment.

We anticipated that the cataract guideline would generate some controversy, primarily because it is unrealistic to expect all physicians in the United States to welcome every new guideline on this or any other subject. But we also recognized that it is quite difficult for today's busy clinician to stay abreast of the latest published studies, or to have the skills to differentiate between methodologically good studies and less-than-adequate research.

Although the AHCPR-supported cataract guideline did not address the level of inappropriate cataract surgery, its recommendations complement conclusions reached by the General Accounting Office in their review of cataract surgery. Both studies share important common recommendations:

- the patient should be a well-informed participant in clinical decisionmaking;
- the appropriateness of cataract surgery depends on the extent of functional impairment; and
- the ultimate decision whether or not to have surgery resides with the patient.

That concludes my opening remarks. I would be happy to answer questions on the cataract guideline or research.

Ms. SMITH. Thank you very much.

Our final speaker is Dr. Earl Steinberg. He is Director of Johns Hopkins' Program for Medical Technology and Practice Assessment. He is also co-principal Investigator of the Agency for Health Care Policy's Research Board on Cataract Surgery. He will be reporting on independent research, the results of which complement the GAO's.

Dr. Steinberg.

STATEMENT OF EARL STEINBERG, M.D., DIRECTOR, JOHNS HOPKINS' PROGRAM FOR MEDICAL TECHNOLOGY AND PRACTICE ASSESSMENT

Dr. STEINBERG. Thank you.

I'd like to thank the Committee and it's staff for having invited me to talk to you today about the performance of cataract surgery in the United States and the role of practice guidelines in outcomes research in health care reform.

As you are all well aware, hardly a day goes by now without there being at least one article in a major newspaper about the importance of bringing health care costs under control. This concern about health care costs is quite appropriate. It is impossible, however, to draw any meaningful conclusion about whether we are spending too much money on health care simply by examining total health care expenditures.

Where the focus really ought to be is on what health benefits we are getting for the health care dollars we are spending and whether we think those health care benefits are worth what we are spending to get them.

When a medical specialty society or a Government panel formulates a practice guideline, each must consider both a scientific issue and a value judgment. The scientific issue is what do available data tell us regarding the benefits, risks, and costs associated with a particular practice or alternative medical practices. The value judgment relates to whether the expected or the potential benefits of a particular practice are worth the associated risks and costs.

Disagreements over the wisdom or the appropriateness of a particular practice guideline may derive from differences in interpretation of available scientific data or to differences in the value judgments that underlie the guideline or both.

Unfortunately, although we spend billions of dollars on health care in the United States, we spend comparatively little on evaluation of the effectiveness and the outcomes of the health care we provide. As a result, there is a huge information deficit associated with current medical practice which takes its toll in the form of tremendous spending on practices that are of no benefit at all and in the form of even greater spending on services which yield very little benefit but which are extremely costly.

I believe this information deficit is a major contributor to our Federal budget deficit. Without addressing this information deficit, health care reform will accomplish much less in terms of controlling costs while preserving quality of care than it otherwise could. Simply put, unless more money and effort is put into evaluating the cost effectiveness of new and old technologies and practices, system level interventions, such as managed competition or budget

caps, will not achieve their desired goals because the physicians whose behavior we are trying to effect will not know which practices to stop performing and which to perform more of.

Against the backdrop of this information deficit, the creation of the Agency for Health Care Policy and Research in 1989 was a breath of fresh air. Over the past 4 years, the agency has funded practice guideline panels to evaluate existing data and to recommend particular practice patterns based on their critical appraisal of that data. The agency also has funded research designed to produce new information regarding the effectiveness and safety of various medical tests and treatments.

Because the scope of the cataract guideline developed by Dr. O'Day's panel is quite broad, there is not sufficient time this morning to discuss the entire guideline. I would, however, like to address one of the major conclusions of the cataract panel, namely that the simple existence of a cataract is not itself a sufficient reason to perform cataract surgery.

The panel concluded that cataract surgery should only be performed when a patient has a symptom or a functional impairment that is likely attributable to a cataract and which is of sufficient concern to the patient to warrant the small but definite risks associated with undergoing cataract surgery.

The important points here are that functional impairment needs to be assessed when evaluating a patient with cataracts and the patient's needs and wants should drive therapeutic decisionmaking. It is against this background that I believe evaluations of the incidence of inappropriate cataract surgery should be assessed.

The main focus of the GAO study was on whether a patient had a problem, be it a symptom such as blurry vision or a functional impairment such as difficulty reading, which was potentially related to a cataract and which was of concern to the patient. The GAO should be commended, in my view, for designing a study which focuses on cataract patients' symptoms and functional status rather than simply their visual acuity.

One must be careful, however, in extrapolating from the GAO's findings and two conclusions regarding the incidence of inappropriate cataract surgery among Medicare patients. My major concern relates to whether the three symptoms and the 12 types of functioning addressed by the GAO adequately cover the gamut of symptoms and types of functional impairment which might justify cataract surgery.

To illustrate my concern, I'd like to turn to data we've collected in our cataract report and I will focus this morning on our observational study of patients undergoing cataract surgery between July 1991 and February 1992.

We collected data in three cities—Columbus, Ohio, which has a low rate of cataract surgery among Medicare beneficiaries; St. Louis, Missouri, which has a medium rate; and Houston, Texas, which has the highest rate of cataract surgery among Medicare beneficiaries in the country. In each city, we recruited approximately 25 ophthalmologists in a stratified fashion based on the volume of cataract surgery each performed annually, and from each of these 25 practices, we recruited up to 12 consecutive patients undergoing cataract surgery for the first time. Each enrolled patient

underwent a 1-hour interview preoperatively and again at 4 and 12 months postoperatively. Patients also underwent clinical exams at the same time periods.

In the interviews, we asked patients about a variety of visual symptoms, their ability to perform many vision-related activities, the overall amount of trouble they had with their vision, and their satisfaction with their vision. All of the symptoms and types of functioning addressed in the GAO study were included in our interview, although we were unaware of the GAO study until after our study was well underway. Several items were included in the interviews which we conducted which were not included in the GAO study, however. The most pertinent of these are shown on this first chart.

We are thus in a position to assess the proportion of patients enrolled in our study who met the GAO criteria for inappropriate surgery and to determine how many of those patients had other types of vision-related problems that might have justified surgery.

A total of 750 patients were enrolled in our study who ultimately underwent cataract surgery. The mean age of patients was 72 years; 63 percent were female and 94 percent were white.

This second chart compares the findings reported by the GAO regarding the incidence of inappropriate cataract surgery with the results of an analysis of data collected in our PORT. As was mentioned earlier, using questions related to symptoms and functioning, the GAO found that 16 percent of patients had no more than a little difficulty with all of the items and that about 2.5 percent had no difficulty with any of the items.

When one looks at the equivalent questions in our interview instrument, the findings are quite similar—13 percent of patients had no more than a little difficulty with all of the items in our questionnaire that were equivalent to the GAO items and 5 percent had no difficulty with any of the GAO items.

As was shown on the earlier slide, however, we examined 10 additional items in our study and when one considers those 10 items in addition to the 15 GAO items, then only 2 percent of patients enrolled in our study had no more than a little difficulty with all of the items and less than 1 percent had no difficulty or problem with all of the items.

We are still examining the representativeness of the population of patients we enrolled but based on our population's responses to questions that are essentially equivalent to those the GAO asked, our study population appears to have been similar to that evaluated in the GAO study.

The next chart and the one after that shows how patients enrolled in our PORT study who would have been considered to have undergone inappropriate cataract surgery based only on the GAO profile of symptoms and functioning fared postoperatively. Using what the GAO termed "the restrictive standard of appropriateness," that is, patients with no more than a little difficulty with each of the GAO items, the vast majority of these patients improved postoperatively.

Using what the GAO termed "the more permissive standard," i.e., that only patients with no difficulty on each of the GAO items were considered to have undergone inappropriate surgery, one-half

to two-thirds of the patients probably considered themselves better off after cataract surgery.

I would draw three conclusions from this analysis. First, one must examine patient's functional status and symptoms and not just their visual acuity to assess the appropriateness of cataract surgery.

Second, estimates regarding the frequency with which cataract surgery is performed inappropriately will vary depending upon the breadth of symptoms and type of functional impairment that one considers. Analysis of our data suggests that the likely rate of inappropriate cataract surgery is probably less than that estimated by the GAO regardless of the magnitude of impairment one feels should be present before cataract surgery is justified.

Finally, judgments regarding the circumstances in which it is appropriate to perform cataract surgery require value judgments to be made regarding how important or significant one considers various types of functional impairment to be. Judgments regarding the appropriateness of cataract surgery in particular circumstances may thus vary from person to person.

I agree with the cataract panel, however, in its recommendation that cataract surgery should not be performed in the absence of symptoms or a functional impairment that is of concern to the patient.

In conclusion, I applaud the Committee's concern about the frequency with which cataract surgery or other medical services are performed unnecessarily. We cannot afford either the human or the economic costs associated with performing tests or for providing treatments that are of no benefit or whose benefits are extremely small in relation to their costs.

The shortsightedness of applying too few resources to medical effectiveness and outcomes research to determine which services provide value and which do not has become painfully clear over the past two decades. Hopefully, President Clinton's proposal for health care reform will result in far more resources being devoted to the evaluation of medical technology and practices and to the development of practice guidelines based on those evaluations.

Thank you very much.

[The prepared statement of Dr. Steinberg follows:]

CATARACT SURGERY, OUTCOMES RESEARCH, AND PRACTICE GUIDELINES -- IMPLICATIONS FOR QUALITY OF CARE AND HEALTH CARE REFORM

Oral Testimony before the
U.S. SENATE SPECIAL COMMITTEE ON AGING

By

Earl P. Steinberg, M.D., M.P.P.
Director, The Johns Hopkins Program
for Medical Technology and Practice Assessment

Mr. Chairman, members of the Committee, and Committee staff, I greatly appreciate the opportunity to testify before you today about performance of cataract surgery in the United States, and the role of practice guidelines and outcomes research in health care reform.

As you are well aware, hardly a day goes by now without there being at least one article in a major newspaper about the importance of bringing health care costs under control, and the pros and cons of alternative strategiea for reigning in health care costs. This focus on health care costs is quite appropriate.

It is impossible, however, to draw any meaningful conclusion about whether we are spending too much money on health care simply by examining total health care expenditures. Where the focus really ought to be is on what health benefits we are getting for the health care dollars we are spending, and whether we think those health benefits are worth what we are spending to get them.

When a medical specialty society, government panel, HMO or insurer formulates a practice guideline, each must consider both a scientific issue -- that is, what do available data tell us regarding the benefits, risks, and costs associated with a particular practice or alternative medical practices -- and a value judgment -- that is, are the expected or potential benefits of a particular practice worth the associated risks and costs. Disagreements over the wisdom or appropriateneas of a perticular practice guideline may derive from differences in interpretation of available scientific data, or differences in the value judgments that underlie the guideline, or both.

Unfortunately, although we spend billions of dollars on health care in the United States, we spend comparatively little on evaluation of the effectiveness and outcomes of the health care we provide. As a result, there is a huge

information deficit associated with current medical practice, which takes its toll in the form of tremendous spending on practices that are of no benefit at all, and in the form of even greater spending on services which yield very little benefit, but which are extremely costly. I believe this information deficit is a major contributor to our federal budget deficit. Without addressing this information deficit, health care reform will accomplish much less in terms of controlling costs while preserving quality of care than it otherwise could. Simply put, unless more money and effort is put into evaluating the cost-effectiveness of new and old technologies and practices, system level interventions, such as managed competition or budget caps, will not achieve their desired goals because the physicians whose behavior you are trying to affect will not know which practices to stop performing and which to perform more of.

Against the backdrop of this information deficit, the creation of the Agency for Health Care Policy and Research in 1989 was a breath of fresh air. Over the past four years, the Agency has funded practice guideline panels to evaluate existing data bearing on the effectiveness and safety of tests and treatments and to recommend particular practice patterns based on their critical appraisal of available data. The AHCPR also has funded research designed to produce new information regarding the effectiveness and safety of various medical tests and treatments.

Because the scope of the cataract guideline developed by Dr. O'Day's panel is quite broad, there is not sufficient time this morning to discuss the entire guideline. I would, however, like to address one of the major conclusions of the cataract panel, namely that the simple existence of a cataract is not itself a sufficient reason to perform cataract surgery. The panel concluded that cataract surgery should only be performed when a patient has a symptom or functional impairment that is likely attributable to a cataract, and which is of sufficient concern to the patient to warrant the small, but definite risks associated with undergoing cataract surgery. The important points here are that functional impairment needs to be assessed when evaluating a patient with cataract, and the patient's needs and wants should drive therapeutic decision making.

It is against this background that I believe evaluations of the incidence of inappropriate cataract surgery should be assessed.

The main focus of the GAO study was on whether a patient had a problem, be it a symptom, such as blurry vision, or a functional impairment, such as difficulty reading, which was potentially related to a cataract and which was of concern to the patient. The GAO should be commended for designing a study which focuses on cataract patients' symptoms and functional status, rather than simply their visual acuity. One must be careful, however, in extrapolating from the GAO's findings to conclusions regarding the incidence of inappropriate cataract surgery among Medicare patients.

My major concern relates to whether the three symptoms and 12 types of functioning addressed by the GAO adequately cover the gamut of symptoms and types of functional impairment which might justify cataract surgery.

To illustrate my concern, I would like to turn to data we have collected in our AHCPR-funded Cataract PORT. I will focus this morning on our observational study of patients undergoing cataract surgery between July 1991 and February 1992.

We collected data in three cities -- Columbus, Ohio, which has a low rate of cataract surgery among Medicare beneficiaries; St. Louis, Missouri, which has a medium rate; and Houston, Texas, which has the highest rate of cataract surgery among Medicare beneficiaries in the country. In each city, we recruited approximately 25 ophthalmologists in a stratified fashion based on the volume of cataract surgery each performed annually. From each of these 75 practices, we recruited up to 14 consecutive patients undergoing cataract surgery for the first time.

Enrolled patients underwent a one-hour interview pre-operatively and at 4 and 12 months post-operatively. Patients also underwent clinical exams pre- and post-operatively.

In the interviews, we asked patients about a variety of visual symptoms, their ability to perform many vision-related activities, the overall amount of trouble they had with their vision, and their satisfaction with their vision. All of the symptoms and types of functioning addressed in the GAO study were included in our interview, although we were unaware of the GAO study until after our study was well underway. Several items were included in the interviews we conducted which were not included in the GAO study, however. The most pertinent of these are shown on the first chart (Attachment 1).

We are thus in a position to assess the proportion of patients enrolled in our study who met the GAO criteria for inappropriate surgery, and to determine how many of those patients had other types of vision-related problems that might have justified cataract surgery.

A total of 750 patients were enrolled in our study who ultimately underwent cataract surgery. The mean age of enrolled patients was 72 years. Sixty-three percent were female; 94% were white. Visual acuity in the operated eye ranged from 20/20 to perception of light only. Median visual acuity was 20/60.

The second chart (Attachment 2) compares the findings reported by the GAO regarding the incidence of inappropriate cataract surgery with the results of an analysis of data collected in our PORT. As mentioned earlier, using questions

related to 3 symptoms and 12 types of functioning, the GAO found that 16% of patients had no more than a little difficulty with all of the items, and that 2.5% had no difficulty with any of the items. When one looks at the equivalent questions in our interview instrument, the findings are similar -- 13% of patients had no more than a little difficulty with all of the items and 5% had no difficulty with any of the 15 GAO items.

As mentioned earlier, however, we examined 10 additional items in our PORT study. When one considers those 10 items in addition to the 15 GAO items, then only 2% of patients enrolled in our study had no more than a little difficulty with all of the items, and less than 1% of patients had no difficulty or problem with all of the items.

We are still examining the representativeness of the population of patients we enrolled, but based on our populations' responses to questions that are essentially equivalent to those the GAO asked, our study population appears to have been similar to that evaluated in the GAO study.

The next two charts (Attachments 3 and 4) show how patients enrolled in our PORT study who would have been considered to have undergone inappropriate cataract surgery, based only on the GAO profile of symptoms and functioning, fared post-operatively. Using what the GAO termed the "restrictive standard of appropriateness" (i.e. patients with no more than a little difficulty with each of the GAO items), the vast majority of these patients improved post-operatively. Using what the GAO termed the "permissive standard of appropriateness" (i.e. only patients with no difficulty on each of the GAO items were considered to have undergone inappropriate cataract surgery), one-half to two-thirds of patients probably considered themselves better off after cataract surgery.

I would draw three conclusions from this analysis: First, one must examine patients' functional status and symptoms, and not just their visual acuity, to assess the appropriateness of cataract surgery. Second, estimates regarding the frequency with which cataract surgery is performed inappropriately will vary depending upon the breadth of symptoms and types of functional impairment that one considers. Analysis of our data suggests that the actual rate of inappropriate cataract surgery is likely to be less than that estimated by the GAO, regardless of the magnitude of impairment one feels should be present before cataract surgery is justified. And finally, judgments regarding the circumstances in which it is appropriate to perform cataract surgery require value judgments to be made regarding how important or significant one considers various types of functional impairment to be. Judgments regarding the appropriateness of cataract surgery in particular circumstances may thus vary from person to person. I agree with the cataract panel, however, in its recommendation that cataract surgery should not be performed in the absence of symptoms or a functional impairment that is of concern to the patient.

In conclusion, I applaud your concern about the frequency with which cataract surgery, or other medical services, are performed unnecssarily. We cannot afford either the human or economic costs associated with performing tests or providing treatments that are of no benefit, or whose benefits are extremely small in relation to their costs. The shortsightedness of applying too few resources to medical effectiveness and outcomes research to determine which services provide value and which do not has become painfully clear over the past two decades. Hopefully, President Clinton's proposal for health care reform will result in far more resources being devoted to the evaluation of medical technologies and practices, and to the development of practice guidelines based on those evaluations. Much can and needs to be done to evaluate the effectiveness, safety and cost of new and established medical practices. It is only through such assessments that we can have any hope of rationally determining which medical practices will improve the health of the public, and which among those can do so at an affordable cost.

Thank you again for the opportunity to participate in this workshop. I would be happy to try to answer any questions that you may have.

Attachment 1

ADDITIONAL ITEMS IN THE CATARACT PORT STUDY

- SEEING STAIRS, STEPS, CURBS
- READING TRAFFIC SIGNS, STORE SIGNS, STREET SIGNS
- DOING FINE HAND WORK (E.G. SEWING, KNITTING, CARPENTRY)
- WRITING CHECKS, FILLING OUT FORMS
- PLAYING GAMES (E.G. BINGO, DOMINOS, CARD GAMES)
- TAKING PART IN SPORTS (E.G. BOWLING, HANDBALL, TENNIS, GOLF)
- COOKING
- WORSENING OF VISION IN LAST MONTH (IN EYE TO BE OPERATED ON)
- TROUBLE WITH VISION
- SATISFACTION WITH VISION

Attachment 2

NO DIFFICULTY (PROBLEM) OR ONLY A LITTLE DIFFICULTY (PROBLEM)

GAO	GAO-E-PORT	PORT
16%	13%	2%

NO DIFFICULTY (PROBLEM)

GAO	GAO-E-PORT	PORT
2.5%	5%	0.4%

Attachment 3

PORT Patients with Little or No Problem on GAO Items but Moderate or Great Problem on Add'l PORT Items

(N = 82)

	Improved after Cataract Surgery
Visual Acuity	95%
Visual Functioning Index	62%
Trouble with Vision	76%
Satisfaction with Vision	85%

Attachment 4

PORT Patients with No Problem on GAO Items but Some Problem on Add'l PORT Items

(N = 31)

	Improved after Cataract Surgery
Visual Acuity	96%
Visual Functioning Index	48%
Trouble with Vision	77%
Satisfaction with Vision	74%

Ms. SMITH. We'd now invite those who are here today to offer comments and questions of the panel. In order to ensure that everyone has an opportunity to be heard we ask that you do the following. Please come up to the mike, ask one question at a time. If there is ample time, you can return to ask a second. When you do come to the mike, please give us your name and if you're not fortunate enough to have a name like Smith, please spell it for the court reporter. Then, please tell us your affiliation and then briefly ask your question.

I, in turn, have asked the panelists to be comprehensive but also brief in their response in order to give everyone an opportunity to speak.

As I said before, the record will be open for 10 days if you wish to submit questions or comments.

We invite anyone from the audience to address the panel.

DUNBAR HOSKINS, EXECUTIVE VICE PRESIDENT, AMERICAN ACADEMY OF OPHTHALMOLOGY

Mr. HOSKINS. Ms. Smith, I'm Dunbar Hoskins, Executive Vice President of the American Academy of Ophthalmology.

I want to compliment the Committee and Senator Pryor and his staff for bringing this issue forward. I think it is an issue of great importance to us in ophthalmology to understand what happens in cataract surgery. We want this data and I compliment the GAO for putting together this report.

I think there is a concern that we have and that is the use of the term "inappropriate." I'd like to ask Ms. Chelimsky about the utilization of that term. As I understand your data, there were 2.5 percent of patients who had neither symptoms nor functional impairment. The Academy's guidelines recognize functional impairment during the interview prior to surgery as an indication for surgery.

It seems to me the table that states "inappropriate surgery," on page 27, I believe, "Estimate of Inappropriate Procedures," seems to inaccurately label perhaps as many as 21.5 percent since they did indeed have symptoms and since cataract does indeed progress. It would seem that this represents a value judgment on the basis of the GAO's investigators rather than a fact.

Could you respond to that, please?

Ms. SMITH. Ms. Chelimsky.

Ms. CHELIMSKY. Basically, those were conditional. What we were saying is, we can't generalize to the Nation. We have no idea how much inappropriate surgery there is. By inappropriate, we mean surgery that has not been performed given an adherence to the particular criterion that we were looking at. Those criteria, except for the one from the American Academy of Ophthalmology, were just potential criteria. So we're not suggesting in any sense that because we looked at four States, we know something about what is happening across the country. There is no effort to generalize this study; it can't be done.

So what we did was look at four potential ways going from what we've called more permissive to more restrictive ways of defining what might be considered inappropriate. Of course, we fixed essen-

tially on the 6 percent which corresponded to the functional impairment one that the AAO has come up with in its guidelines.

Mr. HOSKINS. So then you're not suggesting that as much as 24 percent is inappropriate?

Ms. CHELIMSKY. I'm not suggesting anything about inappropriateness for Medicare patients nationwide. I want to make that absolutely clear. What we're talking about is four States and we are suggesting that if you use one of those criteria, then those might be considered inappropriate. It's a tentative set of findings. This is a developmental field, yet, patient data. You can't make great big, firm statements based on these kind of data.

Mr. HOSKINS. I would hope that you would consider that in your report and perhaps revisions that the term inappropriate may be inappropriate in those cases.

Ms. SMITH. Others that wish to address the panel?

Mr. HUTCHISON. Is the microphone available for comment as well as questions?

Ms. SMITH. Yes, it is, sir.

THOMAS HUTCHISON, PRESIDENT, AMERICAN ACADEMY OF OPHTHALMOLOGY

Mr. HUTCHISON. I'm Thomas Hutchison, President of the American Academy of Ophthalmology.

I too would like to make a comment to Ms. Chelimsky regarding the GAO report. I noted that you correctly perceived that it was the perception of the patient in terms of improvement rather than any objective measurement?

Ms. CHELIMSKY. Absolutely.

Mr. HUTCHISON. Fortunately, we're able to say that in studies about to be released through the medical press, through the Archives of Ophthalmology and also in another major nonophthalmic peer review journal, there are articles that are available now that incorporate both objective as well as subjective response to cataract surgery.

In these reports, we find that the improvement, and noted objectively, sometimes and often will exceed that noted by the patient's perception. We're dealing often with an elderly population who, in your study—I haven't had a chance to review the report except for this morning but I did see the design and the questions asked. These questions ask people to recall several months, even a year longer, what their perceptions were.

We know from these studies that have been produced that in terms of looking at functional decline of activity, the cataract operation is the singular operation in the elderly population to reverse the decline that people have as they grow older. It is an operation that these studies have shown to be 95 percent improvement, objective improvement. When coupled with the subjective response, as you've noted, indicates this operation should not be denied the American public.

We're very concerned in a Senate hearing where the press is available for national comment that as Dr. Hoskins noted, it would be inappropriate to say as much as 25 percent of the operations are unnecessary.

Ms. SMITH. Thank you. Are you inviting them to comment on your comment?

Mr. HUTCHISON. In one moment. I would like to also note that the Government itself, through the Inspector General's office, has estimated that approximately 1.5 percent of cataract operations are unnecessary. We, the American Academy of Ophthalmology and our membership believe that 1.7 percent is a bad number, if indeed that's true.

Other studies the Federal Government has instituted, the preoperative cataract review, which spent over $50 million looking in all States, at the inappropriateness of cataract surgery came up by denying something like .02 percent of operations based on specific review of each and every patient. This indicates to us that the elderly really is being screened in an appropriate fashion.

It would be a tragedy, I believe, if the message came out to the elderly, who sometimes have difficulty in perceiving right and wrong, that the Government would say, we're looking at 25 percent unnecessary surgery. That could possibly influence senior citizens to avoid looking toward the ethical evaluation of their eyes by an ethical physician who will do the surgery when it's appropriate.

The American Academy of Ophthalmology, over the past few years—since 1986—developed preferred practice patterns on which the AHCRP guidelines were based, have provided information statements, patient brochures, code of ethics and the preferred practice patterns, that the principal reason to have a cataract operation is a limitation of the patient's activity, their daily living pattern. We subscribe to that, that it is the patient who should make the decision about whether they have an operation or not, and the physician looking at the patient as a whole, determining what their personal needs are, assessing the rest of the eye besides the cataract to be sure that is indeed the issue.

Thank you.

Ms. SMITH. Dr. Hutchison, I appreciate your comment. It is a bit extended. Is there anything specifically that you would ask the panel to respond to?

Mr. HUTCHISON. Yes. I would ask that the panel, when it looks toward the words "appropriate" and "inappropriate" and when the information comes to the American public that the issues are clear, that the cataract operation as designed is not by multiple studies found to be used in excess.

Thank you.

Ms. SMITH. Allow me to offer what I heard today. This is an evolutionary process of continuing to better inform the medical process, as I described it, both the science and the art of medicine. I hope with the press here today that they will accurately convey that to the American public. It is important for consumers to be aware, in my view, and to be involved. This is an evolutionary process that they too must be a part of.

I speak for myself, as the a daughter of a beneficiary of cataract surgery, and also one that saw some problems as well.

Mr. HUTCHISON. Senator Burns stated it very clearly from a patient perspective, I believe. Senator Burns noted that he had a problem and he had it addressed. We want to see that every American has that opportunity in the new health care reform. We, as

the American Academy of Ophthalmology, applaud your effort, your direction, and we stand to participate in the system to see that every American does have that care.

Ms. SMITH. Would you like to respond?

Ms. CHELIMSKY. Yes. I just wanted to speak to the recall issue which you raised about the ability of people to think back.

I think it's important to recognize that almost every study has a bias of some sort. When you interrogate people before surgery, one of the risks you have is that you might influence them by saying you're going to be looking at this, that or the other thing. When we began our study, we thought of all the possible ways we could do it, and we decided not to do that for that reason.

But you go in and talk to patients too soon after they've had an operation, you have no ability to assess outcomes. So what we did was take a 4 to 10 month window and my sense is that it was not a bad way to go. For one thing, most of the research on recall problems deals with areas where there is some stigma—crime or victimization or perhaps HIV or abortion or something like that. Those are as really present problems; you get distortions in the data. In this case, there was no reason to believe there was any stigma. In addition, an operation is a salient fact in patients' memories.

Third, as to whether people were really senile or couldn't do this, in our investigation of the nonrespondents, we discovered that those were, in large part, the 24 percent that were nonrespondents. We also asked people to let other people help them, if needed. The questionnaire is extremely clear, the questions are mutually exclusive, and my sense is that it's not a bad way to go.

I would agree with what Nancy said a minute ago, this is an evolutionary field and this is a first way of trying to get patient data. I think it's important also to realize that when you talk about evaluating effectiveness, there are some things we can measure easily, but perceptions may not be one of them. So we're just working on this.

Ms. SMITH. Thank you. I'd like to move on to the next person.

KAREN MIGDAIL, FAULKNER & GRAY PUBLICATIONS

Ms. MIGDAIL. My name is Karen Migdail. I'm with Faulkner & Gray Publications.

Is there data aside on concern about the rate of surgery being performed in the United States and is that the reason why a report that was ordered 5 years ago is being released now? The Center said the report was ordered in 1989. Was it a design problem?

Ms. CHELIMSKY. Are you talking about the GAO report?

Ms. MIGDAIL. The GAO report.

Ms. CHELIMSKY. The report was requested in 1989 but at that time, we were looking at ambulatory surgery. We looked at hernia, we looked at a whole number of things and then we thought, we won't do that for this reason or that reason, so there was a rather long period before we actually started our study. I think it was something like 1990 or the middle of 1990. Then because we're a small group—you don't want to hear all these sad stories about what took so long, but it didn't have anything to do with what you suggested.

Ms. MIGDAIL. The press conference that was held when the clinical guideline was released, there was a lot of question about whether Dr. O'Day and Dr. Steinberg were alluding to a high rate of surgery and whether there was reasons for or lack of information from doctors, the idea of a cataract mill. Is there, no matter what the percentages, some concern that this is being done too much?

Ms. SMITH. I will respond possibly after Dr. O'Day.

Dr. O'DAY. I'm aware of those comments and let me state categorically and for the record that I had no knowledge of the study being performed by the GAO until just some weeks ago. It certainly didn't have any influence on the guideline.

The guideline panel did not examine appropriateness of surgery. We did not evaluate any literature on that area. Nor did we discuss that. Our concern was to try and develop proactive guidelines to assist in the care of patients in the future after the guideline was published. We focused on the best interest of the patient and developed the guideline from that perspective, looking at what patients perceive.

There may be a coincidence that there is a converging line there because that is not a new thought; that is a thought that is focusing right across the face of medicine, ultimately what is in the best interest of the patient and how is that perceived.

The guideline panel, in August 1990—when it was set up—had to decide what was the theme for the guideline. It spent a lot of time identifying measures that might determine a successful outcome. The list is published in the guideline, it's not an exclusive list and goes way beyond what the GAO selected, it goes beyond the list that the PORT study under Earl Steinberg's direction suggested.

The point I was trying to make in my comments earlier is that we have to be sure that we are capturing all the measures of functional impairment because if you fail to consider one, then you may falsely deprive a patient of surgery when that patient really needs it. On the other hand, if the tests wrongly identifies patients for surgery, then you may needlessly operate on a patient.

So what it really evolves down to, and the point we were trying to make, was that physicians who are going to sit with the patient and help them make a decision need to understand what functional impairment is about so that the right patients get the appropriate surgery.

Ms. SMITH. Dr. Lavizzo-Mourey wanted to respond as well.

Dr. LAVIZZO-MOUREY. Let me emphasize two points that I made earlier with respect to why we might choose to undertake a guideline in a particular area and hopefully address your concern that there is a feeling that there are too many cataract surgeries.

I emphasize that we look at two criteria—one, whether or not it's a high volume and high cost practice and second, whether or not there is variation in the practice. The fact that there is variation in the numbers of cataract surgeries that are done across the Nation indicates that there is some uncertainty about some of the indications or potential outcomes and that everyone is not doing exactly the same thing. Those, I think, a variation is far and away the most important criteria that we used in deciding to choose cata-

ract as a topic for guideline development, not a concern that there are too many or too few.

Ms. SMITH. One last response from Dr. Steinberg.

Dr. STEINBERG. I just wanted to quickly respond that to my knowledge, there is not a lot of data that addresses the appropriateness or inappropriateness of cataract surgery in any way, or certainly in any methodologically sound way.

By the same token, I'd like to comment on an assertion that was made by some groups of ophthalmologists in conjunction with release of the guideline and that assertion was that if ophthalmologists followed the AHCPR cataract panel guideline, that 30 percent of Medicare patients who need cataract surgery would be denied cataract surgery. My view is that's a completely unfounded, outrageous, ridiculous statement. I have no idea where it's come from, what the basis of it was. No one that made the assertion has been able to come up with one piece of data whatsoever that is consistent with that sort of an estimate.

I think it's important at the same time to say that we don't have good estimates of how much surgery might be performed inappropriately, we certainly have absolutely no data that would suggest that following the cataract guideline would wind up with patients who need cataract surgery not getting it. My own view is that it is quite the opposite and that the percentage of patients who would wind up not getting it who need it would be zero.

Ms. SMITH. Thank you.

Next question?

HARVEY BRENNER, PROFESSOR OF HEALTH POLICY AND MANAGEMENT, JOHNS HOPKINS UNIVERSITY

Mr. BRENNER. Thank you. My name is Harvey Brenner. I'm a professor at Johns Hopkins of Health Policy and Management. I'm the principal investigator of a study of patient outcomes of cataract surgery.

The first set of these papers ought to be published mid-May in the Archives of Ophthalmology.

I have four or five scientific points just to put on the table for the discussion in the workshop.

So much of the discussion by the previous speakers has been on the necessity for requiring patient values inserted as some form of weighting, even of symptoms and functional outcomes. I have not seen any identifier of how patient values themselves are to enter into measurement. In the GAO report, there is not one item of reference to patient values themselves; symptoms, yes, functions, yes, but no values. How are we to enter values?

The second point is that while it seems to be clear that we necessarily require patient information on function and symptoms, do we thoroughly dismiss, completely dismiss the physician input? It is as though in this one area of cataracts, we are not going to pay attention to our expert physicians to advise us.

In particular, I have this in mind. The issue is of the timing of surgery and how serious symptoms are. Let us suppose a physician recognizes that not only is cataract present but is progressing at a certain rate, a degenerative rate, that will put patients at risk for accidents, for mental health problems, for work problems and

the like. These are clinical judgments and they are nowhere to be found either in the AHCPR guidelines, or in the studies to date. Clearly, we cannot have, I think, material bearing on functional outcomes without a sense of the danger we put patients in when we don't take any account at all of clinical judgment.

The third issue is that in the studies we have heard thus far in the preliminary estimates of necessary-unnecessary surgery, while we have a discussion of functional impairment of vision, of the eye itself, we have no discussion of functional impairment, of problems that result from functional deficits in the eye. We have no discussion of work problems, how household problems, of activities of daily living problems, of mental health, of accidents, the entire range of human problems that are the direct or indirect results of the eye functional deficits themselves.

As Dr. Steinberg has pointed out, if we confine ourselves to narrow definitions of functioning, we will get large numbers of unnecessary surgery. If we treat the human condition, the numbers will be very, very much smaller. Some determination needs to be made as to whether we're going to include general human functioning.

The fourth point is this recall issue. I'm sorry to raise this again. I know the GAO report has dealt with this indepth. The problem here is that in evaluation research, we hardly ever find these days a retrospective study based on an evaluation by subjects themselves some many months earlier.

The modern method is always prospective study and it is a little hard to understand why the GAO would put forward a study based on a single sampling rather than the traditional one, two, three samplings and then measure difference. This is particularly a problem, let me point out, because you're aiming to get at very precise numbers, the calculation of percentages and then extrapolate those to large numbers of people, to millions of dollars and so on. So what you're aiming for in the meantime are very precise estimates of patient functioning.

If there are going to be very precise estimates on the basis of individual patients, subjective understanding, how on earth are they going to do that some 7 months after the events occurred?

Thank you very much.

Ms. SMITH. Thank you. I compliment you on your creativity in constructing your four-part question.

Although I think you're addressing the GAO report, I'd like to also invite Dr. O'Day and Ms. Chelimsky, to respond to some or all of your list.

Dr. O'DAY. I would certainly like to thank Dr. Brenner for his thoughtful comments and also for the thrust of his research. We've been aware of that for a while. I thoroughly concur with his central and salient point about the importance of values.

I think there are two sets of values that we need to know about. We need to know about patient values, and that's central to the patient's decision, but we need to know about society values and they need to be out there in front and there are ethical as well as economic dimensions to those.

I think personally we should be careful we don't shelve ethical issues on the basis of economics. We need to confront them face on

and think about their implications for ourselves and the society we're trying to inform.

With regard to the physician input to the decision process, I would like to defend the position the guideline panel took and explain it. What we did, when we started to address the question of where the decision is made and how it must be made, we made a very significant step. We said that the decision has to be made in the context of the relationship that is established between the physician/ophthalmologist who might perform the surgery, and the patient, and that ethical relationship has to be established before the decision can be made. For that reason, we spent a lot of time talking about ethics.

Subsumed into that idea is the notion of the ophthalmologist as a physician, who has had 12 years training in how to look at the patient as a person in the context of their lives. This is because the role of the physician-ophthalmologist is to educate the patient about the benefits and the risks of treatment in the context of his/her life. That's what the ophthalmologist has to do before the decision is made. That is assumed in the document as if it's taken for granted, but it's essential. That's why no one else but the patient, working with the ophthalmologist, can make the decision. It is those two that come to the decision.

So although it's not explicit in the guideline, the theme of the guideline is the relationship that develops between the patient and the ophthalmologist.

Ms. SMITH. Ms. Chelimsky.

Ms. CHELIMSKY. The first question I have here is how to integrate patient values with other values. We didn't try to do that, as you saw. The issue there is that I have as much trouble as you in figuring out how those kinds of perceptions are going to be put together in a quantitative way with other things.

What we were thinking of basically, as you saw, was looking at functions and looking at symptoms which are quantitatively measurable and we dealt with that. I guess the thing I was thinking of with regard to integration was that it would be a great thing if we could get information, just generally speaking, directly from patients at the presurgery decisionmaking time so that it could be considered qualitatively with the other information.

After that, use that as input to the decision of whether surgery should be performed, develop quality assurance mechanisms, but sooner or later, we are going to have to come to grips with the quantitative integration. I agree with you.

Are we throwing out physician input? No. We didn't have any intention of doing that. What we were doing was trying to explore a new way, as I'm sure you realize, of looking at patient data and saying, yes, this stuff is usable, it can be done. I'm not sure how perfect this is, or how perfect anybody's study is.

Finally, the recall issue that you mentioned, well, I think I have as much trouble with any of the ways we've gone about these with regard to biases. They all have problems and I think what we need to do is do them different ways and compare them. So I think what Earl Steinberg did was a really good start, although I'm not sure that our population is related to his population; as he said, he was still looking at the representativeness of it.

So you have these problems no matter how you do it and we are all here at the beginning of a new kind of effort to collect patient data and use it in decisionmaking. This is not the easiest thing in the world, as I'm sure you realize.

Dr. STEINBERG. Harvey, I just wanted to mention that each of the issues you talked about in your question or comment are being addressed in our cataract PORT, so we are objectively looking at patient values in a portion of the PORT that's being conducted right now. We have looked at the relationship between vision-related impairment and overall health status and quality of life. We didn't share that data this morning because there wasn't time but we have been looking at it.

Mr. HUTCHISON. A brief response?

Ms. SMITH. May I first ask if there are others in the room that will be wanting to raise questions, so I can judge the time we have remaining?

Please be brief, then I will ask others to come forward.

Mr. HUTCHISON. On the values matter that occurs and recurs, there are value scales that are presently available and there are ways of weighting with patient values asking directly, as I'm sure you know.

Ms. CHELIMSKY. We know. It's dangerous, you know that.

Mr. HUTCHISON. What I'm particularly interested in with respect to Dr. O'Day's comments and Dr. Steinberg, on the physician input issue if the prognosis is absent, the prognosis itself, no sense of what the clinical judgment would be as to what risk the patient would be put at if surgery were to be delayed. I think the timing issue in all of these estimates is critical.

Thank you.

JEFF ARCHER, SECURE RETIREMENT MAGAZINE

Mr. ARCHER. I'm Jeff Archer. I write for a publication called Secure Retirement Magazine.

A lot of what you talked about sort of hints at arming patients with information but you came up with guidelines for health care providers. Are we at a point where you could give guidelines to patients or consumers if there was advice to broadcast to them? Is there anything we could say at this point or are you not comfortable with that?

Ms. SMITH. Dr. Lavizzo-Mourey.

Dr. LAVIZZO-MOUREY. Let me just emphasize that all of the guidelines that are developed by AHCPR are also made available to consumers in a consumer-oriented format so that they are getting information that is, if not exactly the same, certainly complementary to that being provided in a more technical way to clinicians, physicians, and other health care providers.

In fact, I've just been handed the consumer version which we have available outside so that you can look at it.

SHERYL MATHIAS, AARP

Ms. MATHIAS. Sheryl Mathias from the American Association of Retired Persons.

This is not a question. It's really just a comment and I would ask people to reflect on it.

I get a little disturbed at some of the rhetoric I'm hearing today in this room, comments about elderly persons being unable to distinguish between right and wrong, concerns about recall, concerns about references to mental capacity. I think that most people understand that the practice of medicine has changed a great deal. Most of us, when we deal with our physicians, deal on a much more informed basis. To that effect, I think we need to praise the people who are here as panelists today, their work and the work of some of the commentors on the use of patient information and decisionmaking.

I would hope that we would think that the use of patient information and patient education and decisionmaking extends to older persons who many of us will become if we are not already, and it is equally applicable and there are people who have diminished capacity at many points in their lives, but perhaps there is a way to factor that in also.

I think people are reacting more—perhaps everybody comes down at the same point in the substance but I do get a little worried about concerns that we're throwing away the physician input. Probably the greatest influence on a patient's decision is the input of their physician, so I don't think, no matter what you do, you're going to throw away the physician input.

I would be a little concerned if we had physicians making decisions about surgery over the objection of their patients and I would hope that physicians would be concerned also.

Ms. SMITH. Thank you for that comment.

Ms. CHELIMSKY. I just want to respond briefly about the recall issue. For most of that, it's a methodological issue. It isn't really an issue of the elderly's recall except insofar as that might be a problem, but the recall issue is one that really deals with how much can you be sure of what anyone remembers a certain time back and the research that's involved there. I just didn't want you to think that it was any sort of slap at the elderly.

DONNA DENISON, ASSISTANT TO SENATOR J. BENNETT JOHNSTON

Ms. DENISON. I'm Donna Denison. I'm with Senator Johnston's office.

I'd just note there have been several questions about the interview process. Could you briefly go over that and how the interviews were conducted, and also with specifics to patients who had cataracts removed from both eyes and how that was handled by the interviewers as to whether they interviewed after the first eye and then after both and just kind of relate to the whole interview process?

Ms. SMITH. I'm going to invite Eric Peterson to respond, who was the project manager on the study.

ERIC PETERSON

Mr. PETERSON. In our study, it was not a person-to-person interview, it was a mailed questionnaire. That had many advantages. It meant the people could find the time that it was convenient for them to fill it and were able to give quite a bit of information. It

meant that they could find someone to help them if they needed assistance to fill it out and so on.

We did not specifically separate out people who had either a first or second cataract operation. One of the virtues of the study is that it was a study of all of the cataract operations that had taken place in these four States that had been sampled as a random sample by the PROs in those States.

What that means is that unlike some of the other studies that were being also considered here, we're not excluding from consideration cataract operations that were done by certain types of physicians or certain types of patients. It was basically everybody. So they got a mailed questionnaire. If it happened to have been the second cataract operation that came up in that month for that patient, they were included.

CHARLES SONNENBORN, INSIGHT REPORTS

Mr. SONNENBORN. I'm Charles Sonnenborn with Insight Reports.

Back to the inappropriateness issue if you would, the ophthalmology literature contains a lot of statements that there are roughly three procedures for cataract and that one, intercapsular extraction, may be inappropriate at this point in time.

I wonder why the guideline didn't address this from the standpoint of patient education and I wonder also if those people that are looking at types of cataract surgeries were identifying what type of surgery was used to see if maybe some of the poor results resulted from this type of cataract surgery?

Ms. SMITH. I'm going to ask Dr. Steinberg to address your question.

Dr. STEINBERG. I can address the last part. In our PORT study, we have been looking at what type of cataract extraction was done. In fact, we have it broken down into more than three categories and we've got subtypes of vacoemulsification just as an example. We are in the process of relating those data to the patient outcome.

Ms. SMITH. May I invite others? We have just under 10 minutes left.

BOB ROSENBLATT, LOS ANGELES TIMES

Mr. ROSENBLATT. Bob Rosenblatt, Los Angeles Times.

I have questions for a couple of the panel members. For Dr. Steinberg, I spent a couple of days at an ambulatory clinic in Florida and watched the operations and interviewed the surgeon and his patients. He said that his reading of the guideline showed that at least 2 of the 14 people he operated on would not have received the surgery if the guidelines were compulsory.

If you feel the 30 percent is outrageous and ridiculous, what is a reasonable number for the percentage of surgery that would not be done under the guidelines?

For Dr. Lavizzo-Mourey, the question is, Congress has given the agency hundreds of millions of dollars to set up guidelines and suggestions. If it is not, why do that unless you would hope for it to become mandatory for Medicare to use it to save billions of dollars? What are the prospects of it becoming mandatory?

Third question for Dr. O'Day, I spoke to one of the members of your panel, Eva Skinner, who was the consumer representative,

and her feeling was that some unspecified portion of the money, the $3 billion spent on cataract surgery, might be better used for such things as dental care and helping the elderly pay for prescription drugs which are not covered. How would you respond to that suggestion?

Ms. SMITH. I'm going to take the liberty of the chair at this point. Your third question is a bit off the point of the hearing today. I think the first two are more to the point if the panel would like to respond.

Dr. STEINBERG. The question that was posed to me had to do with what number I think would be a better estimate than the 30 percent number that I said was a figment of somebody's imagination. It's hard to respond to the particular piece of information you gave of the ophthalmologist in Florida having said that 2 of the 14 patients he operated on would not have received surgery.

My response to that is that I don't think he either read the guideline carefully or maybe we ought to look at his practice. My own view is that the proportion of surgery that is appropriate that would be denied or would not be performed under the cataract guideline, my estimate would be zero.

Ms. SMITH. Thank you.

Do you want to respond to the Congressional mandate?

Dr. LAVIZZO-MOUREY. I think Congress, in its wisdom, understood that there was a good deal of misinformation and lack of understanding as well as general gaps in our knowledge about what actually works in medical practice and therefore, recognized the need to fund research and to then disseminate this research through guidelines so that consumers and practitioners will understand how to do a better job.

AHCPR is not a regulatory agency. We are a research agency and an agency that is charged to disseminate its research findings to those who need them.

LISA KIM DAVIS, JOHN HOPKINS UNIVERSITY

Ms. DAVIS. I'm Lisa Kim Davis, Johns Hopkins University, Department of Health Policy and Management.

My question relates to measuring functional deficit. The burden of functional deficit beside being self-reported by the patient, also may be experienced by the caretaker and the family members. Was any attempt made to measure that in your study?

Ms. CHELIMSKY. The GAO study?

Ms. DAVIS. Yes.

Ms. CHELIMSKY. No, we didn't look at caretakers, did we?

Mr. PETERSON. I'm sorry. We had a long questionnaire and we didn't draw on all of the items for this particular report. One of the issues we looked at was to what extent is having surgery done outpatient putting burdens on people outside the health care facility to provide some of that procedure care. So we did ask some questions about that in our survey.

I don't think it's exactly what you were driving at perhaps in terms of the presurgical burdens placed on the other members of the family because the person has a cataract.

Ms. DAVIS. No, what in the outcome is the burden?

Mr. PETERSON. In terms of asking somebody other than the patient, what the outcome was?

Ms. DAVIS. Besides self-reported?

Mr. PETERSON. No, this was from the perspective of the patient.

Ms. SMITH. We have very few minutes left. What I would like is to offer to the panel any last comments they might want to make related to any of the questions or thoughts they have heard since their presentation?

Dr. O'Day.

Dr. O'DAY. Let me get back to the last point that Dr. Brenner raised, the issue of delay. This really relates to the question of guideline development and what guidelines should be.

I think it's important, that our panel certainly tried to avoid creating a cookbook. What the guideline rests upon is the professional expertise of the people who deliver the care. It's implicit in the guideline that the ophthalmologist, the optometrist, the nurses, and all the other people who take care of patients have the requisite training as certified under law to deliver the services. It also explicitly says that they will behave in an ethical manner.

The question of delay is part of the risk benefit discussion that has to take place between the ophthalmologist and the patient as the patient moves toward a decision about cataract surgery. For example, if a person's vision is dropping to the point where they can't drive, the decision is, should I have a cataract operation or not, but the real decision is, should I have the cataract operation or should I stop driving? That's the real decision the patient has to face and that's placed in their lives. The issue of delay is something that is regularly discussed by physicians, by ophthalmologists in any circumstance in medicine when you're talking about treatment. It's implicit in that.

We didn't want to make a cookbook, we wanted to give guidelines that were flexible, and yet were based on what practice is, how practice is delivered and what the science was.

Ms. SMITH. Thank you.

Dr. Lavizzo-Mourey.

Dr. LAVIZZO-MOUREY. I would just close by highlighting the complexity of two particular issues, the measurement of functional status assessments and how they change over time and second, the measurement of treatment outcomes and effectiveness. I think knowing which treatments are effective and how that effectiveness is going to change as new technologies come into play is incredibly complex. The Agency for Health Care Policy and Research is addressing both of these areas.

Ms. SMITH. I thank you.

What I am going to take back for myself today is that this issue is a model of many of the discussions that we will be taking up in the health care reform debate. My hope is that at the same time that we are developing guidelines, we will work to train physicians as well as inform patients to promote effective physician and patient communication.

That's not a concept I heard today. I heard about patient input, I heard about functional assessment. What is needed is an informed communication and decisionmaking process. I believe this is the goal of guideline research.

I thank you all and again, invite you to submit comments for the record.

[Whereupon, at 11:45 a.m., the workshop was concluded.]

APPENDIX

United States General Accounting Office

GAO

Report to Congressional Requesters

April 1993

CATARACT SURGERY

Patient-Reported Data on Appropriateness and Outcomes

GAO
United States
General Accounting Office
Washington, D.C. 20548

Program Evaluation and
Methodology Division

B-239626

April 20, 1993

The Honorable David Pryor
Chairman
The Honorable William Cohen
Ranking Minority Member
Special Committee on Aging
United States Senate

This report describes the symptoms and visual functioning of Medicare patients both before and after they underwent cataract surgery. Because these data come from a random sample of nearly 1,500 cataract patients in California, Massachusetts, Pennsylvania, and Texas, they provide new information on the appropriateness and outcome of cataract surgery from the patient's perspective.

As agreed with your office, we will send copies to the Secretary of Health and Human Services, Administrator of the Health Care Financing Administration, and Administrator of the Agency for Health Care Policy and Research. We will also send copies to other interested parties upon request.

If you have any questions or would like additional information, please call me at (202) 512-2900 or Robert L. York, Director of Program Evaluation in Human Service Areas, at (202) 512-5885. Other major contributors to this report are listed in appendix II.

Eleanor Chelimsky
Assistant Comptroller General

Executive Summary

Purpose

The Medicare program paid for more than 1.3 million outpatient cataract surgeries in 1991. For many patients, cataract surgery provides a dramatic improvement in vision. Yet the potential also exists for patients to suffer complications that result in worse rather than better vision or to have the procedure done when they do not really need it.

Under a larger study undertaken at the request of the chairman and ranking member of the Senate Special Committee on Aging, GAO conducted a survey of Medicare patients who had undergone cataract surgery. The survey responses describe, from the patients' perspectives, their experiences with that surgery. The focus is on the extent of eye symptoms and visual limitations before and after surgery. These data permit an assessment of the outcome of the operation in terms of changes—for better or worse—in those symptoms and limitations after the surgery took place.

A subsequent report will complete GAO's examination of Medicare's quality assurance for outpatient cataract surgery. It will compare the survey responses presented here to the results of current Medicare review procedures for outpatient surgery in order to evaluate the way that Medicare has approached quality assurance for cataract surgery.

Background

A cataract is a clouding of the lens of an eye that typically develops slowly as people get older. Depending on what part of the lens is most affected, and how far along the process has gone, the effect on vision can range from minimal to catastrophic. In most cases, surgical removal of the obscured natural lens, usually combined with the insertion of an artificial lens implant, is the only treatment option available. In recent years, the vast majority of these operations have been performed either in a hospital outpatient department or in a free-standing ambulatory surgery center.

Cataract surgery is not risk-free. A small proportion of patients experience serious complications leading to partial or complete loss of vision. Cataract surgery, therefore, raises two related quality issues. First, to what extent do patients undergo the operation when its likely benefit does not exceed its risks? Second, what proportion of cataract patients ultimately experience improved vision after the surgery?

The American Academy of Ophthalmology has established guidelines for determining the appropriateness (or medical necessity) of cataract surgery. The guidelines emphasize the importance of assessing both the effect of the cataract on the patient's usual activities and the clinical measurement of visual acuity in weighing the likely benefits of surgery against the risks of serious adverse outcomes. According to the guidelines, surgery is not appropriate unless there is evidence that the cataract has led to both clinically measured limitations in visual acuity and functional impairment perceived by the patient in his or her daily life.

In order to obtain data on both presurgical visual limitations and outcomes, GAO developed a survey instrument designed to obtain patients' assessments of their eye symptoms and functional impairments prior to and after surgery. It was sent to a random sample of 1,964 Medicare patients who had recently undergone cataract surgery in California, Massachusetts, Pennsylvania, and Texas. Usable responses were obtained from 76 percent of the sample. The strengths and limitations of using a survey to collect this type of information are discussed in appendix I.

Results in Brief

About three quarters of Medicare patients reported one or more substantial functional impairments affecting their ability to drive, read, or watch television prior to their cataract surgery. These responses generally support the appropriateness of the procedure for those patients. With the inclusion of symptoms such as blurred vision or sensitivity to glare, the proportion of patients with substantial presurgical vision problems increased to 84 percent. Surgery may have been more questionable for the remaining 16 percent of patients, depending on the weight given to "slight" symptoms and functional limitations relative to the risks of the surgery itself.

With respect to the long-term outcomes of the surgery, the overwhelming majority of respondents reported that they improved on one or more symptoms and functional impairments. For about two thirds (66 percent), this improvement was uniform across all dimensions (that is, the symptoms and functions that did not get better at least stayed unchanged). Most of the other patients (30 percent) reported mixed results, with improvements in some symptoms or functional impairments and worsening in others.

Principal Findings

Medical Necessity

The results from the GAO survey provide insight, from the patients' own experiences, on the likely magnitude of inappropriate cataract surgery. However, because inappropriateness has not been clearly defined, the survey results show different amounts of questionable surgery based on different criteria for appropriateness.

If the criterion is that any level of problem with either symptoms or functions (even those the patient considers slight) is sufficient to warrant surgery, responses to the GAO survey show that very few surgeries (2.5 percent) were inappropriate. If the criterion is functional impairment (as it is in the American Academy of Opthalmology guidelines), then 6 percent of respondents' surgeries were inappropriate. This estimate is based on the proportion of patients who indicated they had no limitations in any of the 12 functional activities included in the GAO survey before their cataract surgeries.

If the criterion for inappropriateness escalates from "no problem" to "slight problem," then 16 percent of surgeries were questionable. This proportion corresponds to the 16 percent of patients who indicated they had no more than "slight" problems with either symptoms or functions prior to surgery.

Finally, if the criterion is one of substantial functional impairment, almost a quarter of our respondents (24 percent) would have had inappropriate surgery, reporting to GAO that they had no more than slight problems with visual function before their surgeries.

The data from four states do not allow GAO to make generalizations regarding the likely levels of questionable cataract surgery in the nation as a whole. However, to get some sense of the financial importance reducing such surgery could have, GAO (1) hypothesized that these four states were not unrepresentative of current practice, (2) applied the permissive criterion that, for the surgery to be considered inappropriate, a patient must have reported no functional impairment, and (3) calculated that every 1 percent of cataract surgeries represented approximately $34 million in expenditures for the Medicare program as a whole. Under this scenario, Medicare would have spent approximately $200 million in 1991 for inappropriate cataract surgery.

Outcomes of Cataract Surgery

Concerning long-term changes in both symptoms and functional impairments, the survey responses indicated that a high proportion of patients benefited from the surgery in both areas. Slightly more than 70 percent reported one or more symptoms improved, with none worsening, and almost three quarters (74 percent) said the same for their visual functioning. Most of the rest indicated mixed outcomes for symptoms (18 percent) and functional impairments (12 percent). For this group, some symptoms or functions improved and others worsened. Only a few respondents (5 percent) reported a uniform worsening of symptoms or functional capabilities.

Even patients with no moderate to severe symptoms or functional limitations prior to surgery tended to report modest improvement, particularly in blurred vision. However, the patients who underwent surgery with more substantial visual impairments improved in a larger number of symptoms and functions.

Most patients reported no more than slight interim effects from the surgery itself, such as numbness, bleeding, swelling, or pain. However, there were exceptions, with 1 to 2 percent indicating severe pain or swelling, 7 to 8 percent moderate pain or swelling. Most of these postsurgical symptoms lasted just 1 to 2 days. Adverse events were also rare, with 5 percent of patients reporting an infection, 13 percent a second procedure related to the cataract surgery, and 1.5 percent hospitalization for complications from the surgery.

It is important to note that the findings of this study describe a situation in which expenditures could be reduced and the quality of service could be enhanced at the same time. In effect, if the volume of inappropriate surgeries could be reduced, not only would financial savings be realized but the quality of care for individuals with cataracts would also improve.

Recommendations

This report contains no recommendations.

Agency Comments

GAO deemed it unnecessary to obtain comments on a draft of this report from the Health Care Financing Administration, because it did not address Medicare policies or operations. As mentioned, a subsequent report will examine Medicare's quality assurance procedures for cataract surgery.

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Abbreviations

AAO	American Academy of Opthalmology
GAO	U.S. General Accounting Office
HCFA	Health Care Financing Administration
HCPCS	HCFA Common Procedure Coding System
HHS	Health and Human Services
PRO	Peer review organization

Chapter 1

Introduction

The Medicare program paid for more than 1.3 million cataract surgeries in 1991. For many patients, cataract surgery provides a dramatic improvement in vision. Yet the potential also exists for patients to suffer complications that result in worse rather than better vision or to have the procedure done when they do not really need it.

This report presents our results from a survey of patients who had cataract surgery performed under the Medicare program. It describes, from the patients' perspective, their eye symptoms and visual limitations prior to their operations. It also presents data on the outcomes of those operations. Our concern is with the extent to which the symptoms and limitations that existed before the surgery improved after the surgery. Before outlining the specific objectives of our study, we present some background information on the growth of outpatient surgery in general and on the issues in assessing the appropriateness of performing outpatient cataract surgery on different patients and evaluating the outcome of those operations.

Background

The Growth in Outpatient Surgery

The vast majority of cataract surgeries are now performed as outpatient procedures, either in hospital outpatient departments or in free-standing ambulatory surgical centers. This reflects a larger trend in which surgical procedures in general have shifted to an outpatient setting. In fact, in 1990, 51 percent of all surgical procedures performed in U.S. community hospitals were done on an outpatient basis.[1]

As the volume of outpatient surgery has increased, there has been concern over quality assessment and assurance.[2] The concern arises because less information is generally available in the medical record for an outpatient procedure than for a typical inpatient hospital stay, particularly regarding the outcome of care.[3] This makes it more difficult to conduct the traditional form of quality assurance, historically focused on peer review of hospital medical records.

We were asked by the chairman and ranking member of the Senate Special Committee on Aging to examine quality assurance for outpatient surgery under Medicare. In response to this request, we examined the procedures currently followed by peer review organizations (PROs) to monitor the appropriateness and outcomes of outpatient cataract surgery, gathered data on PRO reviews of actual cases, and conducted a survey of patients to obtain information directly from them regarding their experiences with cataract surgery.[4] The objective of the full study is to see if data provided by patients could usefully supplement the medical record data on outpatient surgery currently used by PROs for such reviews. The results of this analysis and our recommendations for possible changes in Medicare's procedures for reviewing outpatient cataract surgery will appear in a subsequent report. In this report, we present the results from the survey component of our work.

[1]American Hospital Association, "Outpatient Surgery Trends 1980-1990," Ambulatory Care Trendlines: 1992, 1:2 (April 1992), 1, 6, and 10.

[2]Quality assessment involves the application of measures of quality (using either implicit or explicit criteria) retrospectively to the structure, process, or outcomes of care and the monitoring of levels of quality over time. Quality assurance works prospectively and extends the concept of assessment to include the formal organization of activities designed to identify problems in the quality of medical care, determine solutions to them, monitor the effectiveness of the solutions, and institute additional change and monitoring where warranted.

[3]The comparable facility-based record for outpatient surgery is maintained by the hospital outpatient department or free-standing surgical center where the procedure was performed.

[4]PROs are private organizations that contract with the Health Care Financing Administration (HCFA) under the Department of Health and Human Services to monitor the quality of care provided to Medicare beneficiaries in each state. Following instructions outlined by HCFA, the PROs review the medical records of selected cases and perform other functions designed to ensure that all services provided to Medicare beneficiaries are both medically necessary and performed competently.

The data presented in the chapters that follow detail the status of patients prior to their surgery, how they felt in the period immediately following surgery, and the extent to which they experienced improvements in the longer term. These data have implications for two key issues related to quality assurance for cataract surgery: (1) Was the procedure justified to begin with for a given patient? (2) Did the procedure have positive results? Each is discussed in turn.

Medical Necessity for Cataract Surgery

A cataract is a clouding of the lens of an eye. Although there may be many causes, most cataracts among the Medicare population are the result of biochemical changes to the fibers of the lens that occur gradually over time. The lens becomes less uniform, creating variations in its refractivity at different points. This in turn makes the light traveling through the lens scatter, so that the lens is less transparent. These changes are a nearly universal product of aging, with 95 percent of people over 65 losing some clarity in one or both lenses.

In most cases, surgical removal of the obscured natural lens, usually combined with the insertion of an artificial lens implant, is the only treatment option available. However, depending on what part of a lens is most affected, and how far along the process has gone, the effect of the cataract on vision can range from minimal to catastrophic. Many people, particularly in less developed parts of the world, become blind from cataracts. Others with some degree of lens opacity experience no appreciable loss of vision. Therefore, the presence of a cataract does not in itself demonstrate the need for surgery.

Although the risk that cataract surgery will lead to complications impairing the patient's vision is generally quite low, the consequences can be severe. Therefore, a judgment has to be made in each case as to whether the likely benefits of surgery will exceed its risks. The less a cataract affects a patient's vision, the less reason there is to incur those risks by undergoing the surgery. When the probable benefits do not exceed the risks of surgery, the cases are said to lack "medical necessity" or to be "medically inappropriate" for cataract surgery. While there may be financial savings from not performing a cataract surgery that lacks medical necessity, the assessment of necessity does not involve a weighing of medical benefits against financial costs. Rather, looking only at the relative probabilities of both positive and negative effects from the surgery, such patients are considered medically better off if they do not have the operation performed—at least at a given point in time.[5]

Outcomes of Cataract Surgery

Thus, the rationale for performing cataract surgery, given its risks, is the likelihood that a patient's vision will improve following the operation. Once the operation has been performed and sufficient time has passed for the patient to recover from the surgery, one can determine if that prediction proved accurate. Variations in outcome may result from a number of causes, including—but not limited to—the technical competence with which the procedure was performed. Nonetheless, outcome represents a logical "bottom line" for assessing the ultimate effectiveness of a procedure—as implemented—for individuals and groups of patients. The key question is whether the patient has experienced positive change in the visual impairments that prompted surgery in the first place, without introducing complications.

[5]This conclusion may well change if the cataract begins to affect the patient's vision more noticeably.

Assessing Medical Necessity and Outcome

Ophthalmologists assess the need for, and results of, cataract surgery along two distinct dimensions. One is by clinical examination, including the familiar Snellen visual acuity score.[6] The point is to determine how well the patient can see under highly controlled conditions. The second dimension concerns the effect of any visual impairments on the patient's daily activities. In other words, has the patient been unable to carry out activities or had difficulty doing them because of the cataract? Different patients with the same level of clinically assessed acuity may vary widely in the limitations to their daily life, depending on their occupations and interests. For example, sensitivity to glare (a common symptom of cataracts) may affect a taxi driver much more than someone who does not drive.

The importance of both clinical assessments and functional limitations in determining the medical necessity of a cataract operation is underscored in practice guidelines published by the American Academy of Ophthalmology (AAO). These guidelines specify three criteria:

- the patient should perceive a visual disability, relative to the types of activities that he or she otherwise would normally undertake;
- the patient's clinically measured best correctable visual acuity should be 20/50 or worse on the Snellen scale;[7]
- the patient should have been informed of the risks and benefits of surgery and made his or her own decision that the benefits outweigh the risks.[8]

The guidelines state that all three criteria must be met for the surgery to be considered appropriate.[9]

Objective, Scope, and Methodology

Objective

The objective of this portion of our study was to describe (1) the extent of visual symptoms and functional limitations perceived by Medicare cataract patients prior to surgery and (2) the change in those symptoms and functional limitations experienced by patients following the procedure. The emphasis on patient perceptions as opposed to clinical assessments of medical necessity and outcome reflected the aim of the larger study to supplement the information already collected by the PROs, which is primarily clinical.

Scope

We focused our study on California, Massachusetts, Pennsylvania, and Texas, rather than attempting to collect information from patients nationally. This focus stemmed from our objective in the other part of this study to compare patient-provided information with the results of PRO reviews. Thus, we took for our random sample of patients the sample of Medicare cataract surgery patients drawn by the PROs in each of the four states.

We intentionally picked four relatively large states, so that the patients the PROs selected to review at a specified time point would provide us with a reasonably large number of patients to survey. At the same time, one would expect to find a good deal of variation within and among these states, given their size and geographic dispersion, with respect to patient characteristics and physician practice styles.

[6]The Snellen scale (20/20, 20/40, etc.) assesses distant visual acuity in terms of the patient's ability to identify alphabetic letters of decreasing size.

[7]Or 20/40 or worse with a patient's complaints of disabling glare.

[8]American Academy of Ophthalmology, "Cataract in the Otherwise Healthy Eye," September 16, 1989, p. 6.

[9]There are two other circumstances in which the guidelines note that cataract surgery would be indicated: (1) patients with lens-induced diseases and (2) situations where the ophthalmologist needs to be able to see through the lens more clearly to treat other eye problems.

This focus on four states means that we cannot generalize our findings to the nation as a whole. The descriptive statistics generated by the study on the level of eye symptoms and functional limitations prior to cataract surgery and the distribution of favorable and adverse outcomes following surgery apply only to those four states.

In this report, we present the data provided by our respondents in the four states as a whole. This approach allows for greater clarity in examining relationships in the data generated by the survey, since all the respondents had the same procedure and answered the same questions about their individual experiences. However, we point out the instances in which the pattern of responses differed significantly among the states.

Methodology

We chose a survey as our basic data collection strategy because most of the data we wished to gather concerned patients' experience and perceptions, and the survey has long served as a primary means for investigating such things. A survey can obtain the information directly from individuals, using standardized questions and response categories to maximize the comparability of the data produced over large numbers of respondents.

Nonetheless, surveys can, under certain circumstances, produce misleading results. We identified several factors that could have affected the ability of our specific survey instrument to produce accurate information. These included the content and wording of survey questions and the potential for biased results arising from any systematic differences between respondents and nonrespondents, problems in recall, or variations among respondents in their willingness to report certain kinds of events or perceptions. Appendix I examines in detail the potential effect of each of these methodological issues on our analyses. In general, we found that none of these factors is likely to have biased our results to a substantial degree.

We sent our survey to the Medicare cataract surgery patients in the four states that had been selected by the PRO for ambulatory surgery review in November 1990.[10] The vast majority of these (97 percent) involved a single procedure, extracapsular extraction of a cataract with insertion of an artificial lens (HCPCS code 66984).[11] To ensure that our comparisons across cases were not biased by differences in the procedure performed, we limited our analyses to the cases that involved this specific procedure.

Our findings from the survey of patients are strengthened by a relatively large sample and high response rate. Of the 1,964 cataract cases selected for review by the four PROs, usable responses were obtained from 1,488, or 75.8 percent.[12] This rate is calculated from the total set of cases selected by the PROs. Therefore, nonresponse includes all those for whom no survey results were obtained for any reason (death, mental infirmity, inaccurate mailing addresses, and so on).

[10]One exception should be noted; the Massachusetts PRO selected cases for postsurgery review from among those that had required prior authorization (primarily cataracts and bunionectomies) twice a year rather than every month. It therefore included cases from roughly the same time period as in the other states but with somewhat greater dispersion with respect to the date on which the procedure was performed.

[11]HCPCS stands for the HCFA Common Procedure Coding System. It refers to the comprehensive list of individual medical procedures for which HCFA reimburses physicians under Medicare.

[12]The breakdown among the states was 628 sent with 461 returned from California, 445 sent with 349 returned from Massachusetts, 403 sent with 318 returned from Pennsylvania, and 478 sent with 360 returned from Texas.

These samples and response rates are large enough that standard errors are quite small—between .258 and 1.30—for the group of cataract patients as a whole, and still modest—.558 to 2.80—for the smallest sample from an individual PRO.[13] This means that the results obtained from our samples should accurately represent the populations from which they were drawn to within a few percentage points.[14]

Strengths and Limitations of the Survey

Previous Studies of Cataract Surgery

The strengths of our study can best be discussed in the context of other studies on the appropriateness and outcomes of cataract surgery. While these studies have generated information on these issues, their research objectives differed considerably from ours. As a result, they have collected less extensive data from patients concerning their condition before and after surgery. Moreover, the design of these studies sometimes complicates the interpretation of these data with respect to appropriateness and outcomes.

For example, the most closely related study was produced by the office of the inspector general in the Department of Health Human Services (HHS).[15] This study involved a survey of Medicare outpatient surgery patients that included cataract operations along with endoscopy, colonoscopy, and bunionectomy. The survey contained a limited number of questions on symptoms, functional limitations, and complications of surgery and an overall assessment on whether the patient's vision had improved. The primary purpose of this study was to compare hospital outpatient departments and free-standing ambulatory surgery clinics. The sample was therefore structured to include patients from 11 states with relatively large numbers of clinics and then stratified to provide equal numbers of patients from each type of facility. This makes it difficult to interpret the results reported for the group of patients as a whole, because they were not weighted to take account of the much larger number of patients treated in hospital outpatient departments.

A second survey of ambulatory surgery patients, including cataract procedures, was conducted by the American Association of Retired Persons.[16] This study included several questions replicated from the HHS inspector general study on postsurgical complications and overall improvement in vision (but not those on presurgical symptoms and functional limitations), as well as some additional items regarding patients' condition at time of discharge. The main focus of this instrument was on the extent of burden imposed on patients and their families by having recovery take place at home rather than in the hospital. Limited information on outcomes, and none on presurgical conditions, emerged from this study.

A third study addressed the appropriateness of cataract surgery more directly but did so using the same methodology currently employed by PROs—peer review of medical records.[17] This was another HHS inspector general study, a companion to the one mentioned above, in that it assessed records for the same sample of patients as was sent the questionnaire in the first study. Therefore, the particular structure of that sample poses equivalent problems of interpretation for the population as a whole, as distinct from specific comparisons of hospital outpatient departments and free-standing ambulatory surgery clinics.

Our study builds on these prior research efforts by collecting more detailed information from patients on specific symptoms and functional impairments both before and after their cataract surgery. Moreover, our subsequent report will link these data to the results of the existing system for assuring quality of care for Medicare patients undergoing cataract surgery.

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[13]These standard errors are calculated for percentages—for example, the percentage of cases that experience a given type of outcome. The range of standard errors reflects the fact that standard errors increase, for a given sample size, as the results move from the extremes (1 percent or 99 percent) toward an even split (50 percent).

[14]For example, a rate of 10 percent with a standard error of 1.68 means that there is a 95 percent chance that the actual rate in the population from which the sample was selected is somewhere between 6.70 percent and 13.30 percent (10 plus or minus 1.68 x 1.96).

[15]U.S. Department of Health and Human Services, Office of Inspector General, Patient Satisfaction with Outpatient Surgery: A National Survey of Medicare Beneficiaries (Washington, D.C.: December 1989), p. 8.

[16]Shelah Leader, The Outpatient Surgical Experiences of Aged Medicare Enrollees, American Association of Retired Persons, Public Policy Institute (Washington, D.C.: August 1990).

[17]U.S. Department of Health and Human Services, Office of Inspector General, Outpatient Surgery, Medical Necessity, and Quality of Care (Washington, D.C.: February 1991), pp. 6 and B-1.

Patient Reports

The primary strengths and limitations of the study both derive from the fact that the information comes directly from patients. To understand these strengths and limitations it is helpful to review the issues regarding medical necessity and outcomes that patient-based reports, on their own, can address.

As mentioned above, AAO has issued guidelines on when cataract surgery is appropriate. These guidelines require that visual function be impaired as a necessary condition for surgery. Since the patients are the best source of information on their ability to perform activities of daily living, the reports of patients (either directly or secondhand through a physician) are essential for assessing adherence to the AAO's guidelines for appropriateness. The major contribution of our survey is that, compared to previous studies, it has gathered more comprehensive information directly from large numbers of patients on the extent to which their visual function was limited prior to cataract surgery. Therefore, it provides the best currently available data on the degree of adherence to this part of the AAO guidelines.

Obtaining comparable information directly from these patients on their postsurgical experiences also enabled us to analyze the short-term and long-term outcomes of cataract surgery from the patient perspective. These outcomes included reactions to the surgery itself (pain, swelling, and so on) as well as changes in symptoms and visual capacity. In particular, we collected detailed information on the extent to which patients found that specific functional impairments and symptoms changed for the better or worse after surgery.

However, as with the assessment of appropriateness, patient-reported data are highly relevant but not all-inclusive. Both clinical observations or tests and patient perceptions of their own experience play a role in measuring the results of cataract surgery. Clearly, it is with respect to the perceptual dimension that our study presents more comprehensive and reliable data than has yet been available.

Thus, interpretation of the survey results needs to take account of two points: (1) other (primarily clinical) data are also germane in making a full assessment of the appropriateness of cataract surgery and its outcomes and (2) patient-reported information on its own provides stronger evidence regarding some aspects of these issues than others.

The AAO guidelines require both clinical and patient-based information to establish the appropriateness of surgery. That means that reports by patients indicating little or no diminution of visual functioning prior to the surgery are sufficient to put into question the appropriateness of the procedure. However, the opposite is not true—that is, reports by patients of poor visual functioning would not suffice to ensure appropriateness. Patients reporting major visual limitations prior to surgery might still not meet the test for appropriateness if their clinically measured visual acuity exceeded the specified threshold. Therefore, our estimates of potentially inappropriate cataract surgery may be somewhat conservative, in that they will miss any cases that met the functional criterion but not the clinical one.

It is also important to keep in mind that some important outcomes of surgery will not necessarily affect a patient's perceptions of symptoms or visual functioning. For example, glaucoma may emerge or worsen following cataract surgery without causing immediate problems that the patient would notice. Thus, the changes in symptoms and functional impairment reported by patients, while critical to an examination of overall outcomes, do not encompass all dimensions relevant to a comprehensive assessment.

A related issue concerns the evaluation of the process of care. Basically this refers to the extent to which the treatment given patients corresponds to patterns of approved practice within the medical community. Both outcome and process are considered components of the overall quality of care but the two are not necessarily linked. Closely following accepted medical practices will not always lead to favorable outcomes, while divergence from those standards will not always have negative consequences.

Patients can generally provide better information on outcomes, at least those that reflect changes in symptoms and functional capacity, than they can on adherence to standards of medical practice.[18] This is of greatest consequence in attempting to answer the question of why adverse outcomes occurred. We did collect data in the survey that could be used to identify patients who have a higher than average risk of poor outcomes (for example, those with other medical conditions, poor overall health status, and the like). However, a key question for quality assurance is how the physician treating each of those patients responded to those factors. Only a medical record review can adequately address that issue.

Report Overview

Chapter 2 describes the nature and extent of eye symptoms and visual limitations that our survey respondents reported they had prior to surgery and relates these responses to the issue of medical necessity. Chapter 3 examines the outcomes of these procedures in terms of the long-term changes reported by patients in their symptoms and functional abilities following surgery, as well as more interim outcomes related to the surgery itself. Chapter 4 then analyzes how patients with more substantial functional impairments and symptoms fared in terms of long-term outcomes compared to those patients whose relatively mild symptoms or functional difficulties made the appropriateness of their cataract surgery more questionable.

[18] By contrast, patients are the primary source for data on a different dimension of health care process, the quality of personal interactions.

Chapter 2

The Condition of Patients Prior to Cataract Surgery

A key objective of the survey was to obtain detailed information about the patients' eye symptoms and visual impairments before the surgery took place. In this chapter we begin by simply describing the distribution of eye symptoms and functional impairments reported by our respondents. Next we examine the implications of those symptoms and impairments for the appropriateness of the cataract surgery in light of the AAO guidelines described in chapter 1.

Functional Impairment and Symptoms Before Surgery

Our survey inquired about vision problems in two broad categories: functions and symptoms. Because visual functioning relates most directly to the AAO guidelines, we discuss it first.

Extent of Impaired Visual Functioning Prior to Surgery

The survey assessed visual functioning through a set of questions that asked respondents to describe their difficulty prior to surgery in watching television, reading, and driving.[1] Respondents could choose among four levels of difficulty: no, little, moderate, and great, plus a "not applicable" category for those who did not engage in the specified activity. For each of these three areas, four questions addressed specific aspects of that activity:

- watching television: seeing the picture at all, seeing colors, recognizing people and objects, and reading words on the screen;
- reading: headlines, large-print books, standard text, and telephone books;
- driving: short distances in daytime, long distances in daytime, short distances at night, and long distances at night.

The responses to these questions, shown in table 2.1, indicate two overall patterns. First, except for the visually most stressful activities, the majority of patients reported relatively unimpaired eye function.[2] Those experiencing little or no difficulty substantially outnumbered those having moderate to great difficulty in 8 of the 12 activities. For 2—reading words

[1]While certain other activities are sometimes used to assess visual functioning (such as needlework), we judged that reading, watching television, and driving would be relevant to the largest proportion of patients.

[2]The relatively large number of "not applicable" responses makes this finding more tentative for driving than for reading and watching television. The "not applicable" response may or may not indicate a respondent's eyesight: some may have such poor vision as to preclude driving, while others may not drive for reasons quite extraneous to eyesight. The fact that women were more than twice as likely to respond "not applicable" for each type of driving than men (both before and after surgery) suggests that much of the "not applicable" response may not relate to eyesight.

on television and driving short distances at night—about as many reported moderate to great difficulty as little or none. Only for reading telephone books and driving long distances at night did the group experiencing moderate to great difficulty clearly predominate.

Table 2.1: Extent of Impaired Visual Functioning Prior to Surgery Reported by Patients

Activity	Amount of difficulty None	Little	Moderate	Severe	Not applicable
Watching TV					
Seeing picture at all	57.1%	21.6%	14.0%	5.3%	2.0%
Seeing colors	63.8	16.8	10.7	7.2	1.5
Recognizing people	45.2	25.1	19.3	8.9	1.5
Reading words on screen	23.2	24.6	27.7	21.5	3.0
Reading					
Headlines	61.1	14.9	10.7	9.6	3.7
Large print	64.1	13.1	8.7	4.3	9.8
Standard text	29.1	26.2	20.7	18.6	5.3
Telephone books	16.0	24.5	20.9	32.9	5.6
Driving					
Short distances daytime	41.5	13.1	7.9	3.0	34.5
Long distances daytime	24.6	16.7	10.2	5.4	43.0
Short distances night	11.4	15.0	10.9	15.6	47.1
Long distances night	5.7	9.0	10.9	18.5	55.8

Second, patients varied considerably in the degree of difficulty that they reported within each of these activities. Ten to 20 percent indicated substantial impairment, having moderate to great difficulty, even with such basic tasks as recognizing colors or reading large-print books. Conversely, a somewhat larger group, 15 to 40 percent, indicated little or no difficulty on the 2 activities that the group as a whole found most taxing. On several items, we found an almost even split among those experiencing none, a little, moderate, and great difficulty.

This pattern held for each of the four states but with variation among them. For example, a somewhat higher proportion of respondents in Texas reported moderate to severe difficulty in performing 11 of these functions than those in the other states.

Extent of Eye Symptoms Prior to Surgery

In addition to functional limitations, cataracts often have symptomatic effects that may affect patients more or less severely. We asked respondents whether they had experienced any of the following six symptoms in the 4 weeks prior to their surgery and, if so, how much it bothered them on a scale ranging from not at all to severely:

- fuzzy, blurred, or clouded vision;
- vision restricted by glare or excessive sensitivity to light;
- double vision;
- itching or burning in the eye;
- floaters (small visual obstructions);
- a feeling of something in the eye.

The first three are classic symptoms of cataracts; the last three are other problems that could emerge either before or following surgery. Table 2.2 shows the proportion of patients in the four states who reported having each of these symptoms immediately prior to their cataract surgery and the extent to which they were bothered by them.

Table 2.2: Extent of Presurgery Eye Symptoms Reported by Patients

Symptom	Patient did not have symptom	Patient had symptom and was bothered			
		Not at all	A little	Moderately	Severely
Blurred vision	12.0%	5.2%	23.7%	31.7%	27.4%
Sensitivity to glare	23.4	6.0	25.4	26.3	18.8
Double vision	75.5	3.2	9.9	7.7	3.8
Itching	55.0	8.2	20.2	12.2	4.4
Floaters	40.3	15.4	24.1	14.4	5.7
Feeling of something in eye	52.5	6.9	20.8	13.1	6.7

Blurred vision and excessive sensitivity to glare were, as expected, the two most common symptoms reported by our respondents. They appeared in 88 and 77 percent of these patients, respectively. However, the extent to which these symptoms affected patients varied markedly. A few, 5 to 6 percent, had these symptoms but were not bothered by them at all. Another 25 percent, approximately, experienced little bother. Fifty-nine percent had moderate to severe difficulty with blurred vision, 45 percent with glare.

As we found for functional impairments, the broad pattern of these results was the same in each state. Still, the proportion of patients reporting that they were bothered by one of these symptoms moderately or severely prior to their surgery was consistently highest in Texas and lowest in Massachusetts for all six symptoms.

Relationship of Patient-Reported Condition to Appropriateness of Surgery

As the preceding section made clear, patients experience symptoms and functional limitations prior to surgery to a greater or lesser degree. How much is enough to justify surgery? In order to draw any inferences about the appropriateness of cataract surgery from patients' reports on eye functions and symptoms, one has to have some standard that distinguishes appropriate from inappropriate. The AAO guidelines provide no specific guidance on this point, leaving it, rather, to the patients to judge whether they have visual disabilities whose likely improvement from cataract surgery would produce a benefit that exceeds those risks. However, the data from our survey allow one to see the proportion of procedures currently performed that would appear to have questionable necessity at different thresholds or standards for appropriateness.

Generally, our analysis considers two thresholds of appropriateness:

- a permissive standard that accepts any level of reported problems involving symptoms or functional impairments as indicative of the need for surgery and
- a more restrictive standard that calls for one or more symptoms or functional limitations at a moderate or severe level.

The group of patients who meet the first standard but not the second are those who have only "slight" problems involving eye symptoms or functional capacity. The choice between the permissive and restrictive standards would rest on a judgment weighing the likely benefits of surgery for this group against the risks inherent in the surgery itself.

Appropriateness Based on Functional Impairments

We assessed the appropriateness of the cataract surgery with respect to functional limitations by determining the maximum difficulty for any of the 12 functional activities. Next, we applied our two appropriateness standards as follows. The permissive standard raises questions about the appropriateness of cataract surgery if the patient had no difficulty at all in any of the 12 activities. The restrictive standard, by contrast, questions the appropriateness of surgery for all cases in which the patient reported no more than slight difficulty with any of these activities.

The results of this analysis are presented in table 2.3. Just 6 percent of all respondents had no difficulty before surgery with any of the activities. That figure increases to almost 10 percent if one excludes the two most difficult activities: reading telephone books and driving long distances at night. However, setting the threshold of appropriate surgery at moderate or severe difficulty for at least one activity increases the questionable group to 24 percent (6 percent plus 18 percent), or 32 percent excluding the 2 most difficult tasks. Thus, a clear majority reported substantial functional impairment, but a sizable minority did not.

Table 2.3: Highest Level of Presurgery Visual Impairment Reported by Patients for Any of Twelve Functional Activities

	Amount of difficulty			
	None	Little	Moderate	Severe
Greatest difficulty reported for any of 12 functions	6.0%	18.0%	25.4%	50.5%
Greatest difficulty reported for any of 10 functions[a]	9.7	22.3	29.0	39.1

[a]Excludes driving long distances at night and reading telephone books

Appropriateness Based on Reported Symptoms

We performed a parallel analysis on the data we collected from patients regarding the extent to which they experienced certain eye symptoms prior to surgery. Thus, we established for each patient the greatest degree of bother that he or she reported for any of the six symptoms. We also did this for just the three classic cataract symptoms—blurred vision, sensitivity to glare, and double vision. These figures appear in table 2.4.

Table 2.4: Highest Level of Presurgery Eye Symptoms Reported for Any of Six Symptoms[a]

Symptom	Patient did not have symptom	Patient had symptom and was bothered			
		Not at all	A little	Moderately	Severely
Most severe response among all six symptoms	3.0%	6.2%	20.9%	34.9%	35.1%
Most severe response among blurred vision, glare, and double vision	6.0	5.6	21.5	33.6	33.3

[a]The six symptoms are blurred vision, sensitivity to glare, double vision, itching, floaters, and a feeling of something in the eye

As before, we gauged appropriateness according to a permissive and restrictive standard. The permissive standard raised questions about operations only when the patient either did not have or was not bothered at all by any of the six symptoms. The restrictive standard added to the questionable group those who experienced no more than a slight degree of bother from any of the symptoms.

Generally, somewhat more cataract operations would appear to have questionable appropriateness based on symptoms than functional limitations. In terms of the permissive standard, 3 percent of patients did not have any of the symptoms, and another 6.2 percent was not bothered at all by any of them, for a total of 9.2 percent. That figure increases to 11.6 percent if one considers only the three classic cataract symptoms of blurred vision, sensitivity to glare, and double vision. Adding cases that were bothered only slightly by their symptoms increases the proportion of questionable cases to 30.1 percent for all six symptoms and 33.1 percent for the three classic symptoms.

Visual Functioning and Eye Symptoms Combined

Finally, we examined the overlap between reported problems involving visual functioning and symptoms. We did this using both the permissive standard we outlined above, where a minor problem on one or more symptoms or functional activities is sufficient to justify the procedure, and the more restrictive standard, which requires a moderate or severe problem on at least one symptom or functional activity. The proportion of patients who would be considered appropriate under each standard for both functions and symptoms taken together, compared to what it would be for functional impairments and symptoms separately, is shown in table 2.5.

Table 2.5: Proportion of Cataract Patients Meeting Permissive and Restrictive Standards for Appropriateness Based on Patient-Reported Eye Symptoms and Functional Impairments

Standard for medical necessity	Threshold met for			
	Functions	Symptoms	Either symptoms or functions	Neither symptoms nor functions
Permissive[a]	94.0%	90.8%	97.5%	2.5%
Restrictive[b]	75.9	69.9	83.7	16.3

[a]The permissive standard considers cataract surgery appropriate whenever the patient reports any problem involving symptoms or functional impairments, including those of little or slight magnitude

[b]The restrictive standard considers cataract surgery appropriate if the patient reports at least one problem at a moderate or severe level involving symptoms or functional impairments.

Under the permissive standard, the vast majority of cases would appear appropriate whether one looks solely at functional impairments (94 percent), solely at symptoms (90.8 percent), or at both together (97.5 percent). Considering both functional limitations and symptoms makes more of a difference under the restrictive standard, with 83.7 percent of cases meeting the standard compared to 75.9 percent looking at functions alone. This means that taking account of both

patient-reported visual impairments and symptoms but excluding cases with no more than minor problems, approximately 16 percent of respondents had operations of questionable appropriateness.

Under both standards, the pattern was similar across the four states, though with some variation in the proportion of cases that did not meet the threshold of medical necessity for both symptoms and functions. This group ranged from 3.2 percent in Pennsylvania to 1.4 percent in Texas under the permissive standard and from 21 percent in Massachusetts to 12 percent in Texas under the more restrictive standard.

Conclusion

The proportion of cataract procedures identified as having questionable appropriateness ranges substantially—from a few percent to about a quarter—depending on the threshold applied and the scope of relevant indications (functional limitations and symptoms). Since the AAO guidelines focus on functional limitations, at least for the component based on information provided by patients, one can look in the first instance at the survey questions relating to driving, reading, and watching television. However, one may wish also to consider relief of symptoms as a rationale for surgery, regardless of whether they adversely affect the patient's ability to function in daily life. This would argue for an approach that took account of both functions and symptoms. However, as table 2.6 makes clear (at least for the population we sampled), this choice has less effect on the overall estimate of inappropriate surgery than does the decision on whether to consider problems that the patient views as minor or slight to be sufficient to justify surgery.

Table 2.6: Estimates of the Proportion of Inappropriate Cataract Surgeries Based on More or Less Restrictive Criteria

Surgery considered inappropriate when severity of patient's worst problem is no greater than	Type of problem considered	Estimate of inappropriate procedures
None	Functions and symptoms	2.5%
None	Functions only	6.0%
Slight	Functions and symptoms	16.3%
Slight	Functions only	24.0%

Because of the magnitude of total Medicare expenditures for cataract surgery, even small changes in the rate of inappropriate surgery might have notable financial implications. Exactly how much money could be "saved" on a continuing basis by reducing inappropriate cataract surgeries is difficult to estimate. That figure would require, at a minimum, knowledge of how many cataracts would later progress to the point where they did cause functional impairment (and when that occurred), trends in the incidence of cataracts in upcoming years, and changes in the costs of the procedure. However, to provide a sense of how much was spent in a recent year on inappropriate surgery for cataracts, we did the following:

- we hypothesized that the data from the four states were not unrepresentative of current practice in the nation as a whole,
- we applied the permissive criterion that a patient must have reported no functional impairment for the surgery to be considered inappropriate, and
- we calculated that every 1 percent of cataract surgeries represented approximately $34 million in expenditures for the Medicare program as a whole.[3]

Under this scenario, Medicare would have spent approximately $200 million in 1991 for inappropriate cataract surgery.

The actual expenditures on unnecessary cataract surgery in 1991 is uncertain, as is the long-range savings that could be obtained through a decline in inappropriate cataract surgery in future years. However, any success in reducing the level of inappropriate cataract surgery has the clear advantage of combining potential financial benefits with enhanced quality of care, since fewer patients would be exposed unnecessarily to the risks of surgery.

[3]Medicare expenditures for cataract surgery in 1991 were estimated to total $3.4 billion. Denis M. O'Day et al., Cataract in Adults: Management of Functional Impairment (Washington, D.C.: U.S. Department of Health and Human Services, Agency for Health Care Policy and Research, February 1993), p. 21.

Chapter 3

Outcomes of Cataract Surgery

This chapter examines the outcomes of cataract surgery from the patient's perspective. Here we take as a baseline the presurgical symptoms and visual limitations described by the respondents to our survey and assess the long-term vision outcomes of the surgery in terms of any changes reported in those symptoms and limitations by each patient. In addition, we consider a number of transient symptoms and adverse events to evaluate potential interim outcomes of the procedure, such as pain, swelling, infection, required periods of recovery, and so forth. These may be considered part of the "cost" of the surgery to the patient, against which to weigh the potential benefits of improved vision over the longer term.

Long-Term Outcomes

Although in individual cases other long-term outcomes may ensue from cataract surgery, the main question is how much better can patients see once they have recovered from the operation. We can address this issue by comparing what our respondents reported about their symptoms and functional capabilities when they completed the survey to their assessment of their condition on the same dimensions prior to surgery. These responses should reflect the final outcome of the surgery, since the shortest interval between the date of the operation and completion of the questionnaire was 4.8 months (median 7.3 months).

Tables 3.1 and 3.2 show, for all respondents, the proportion reporting that their functional capabilities and symptoms improved, stayed the same, or got worse. Change in this analysis represents any increase or decrease in the extent to which the patient had difficulty with a functional activity or was bothered by a symptom.

Table 3.1: Proportion of Patients Who Reported Their Visual Functioning Improved, Stayed the Same, or Worsened After Surgery

	Change after surgery		
Activity	Better	Same	Worse
Watching TV			
Seeing picture at all	36.1%	60.6%	3.2%
Seeing colors	30.2	67.2	2.6
Recognizing people	44.4	51.9	3.7
Reading words on screen	62.3	33.3	4.4
Reading			
Headlines	32.0	65.7	2.3
Large print	24.1	73.9	2.0
Standard text	56.2	38.4	5.4
Telephone books	59.6	35.9	4.4
Driving			
Short distances daytime	34.1	64.2	1.8
Long distances daytime	47.0	48.9	4.1
Short distances night	61.9	33.9	4.3
Long distances night	61.1	35.7	3.1

Table 3.2: Proportion of Patients Who Reported Their Eye Symptoms Improved, Stayed the Same, or Worsened After Surgery

	Change after surgery		
Symptom	Better	Same	Worse
Blurred vision	77.8%	18.8%	3.4%
Sensitivity to glare	53.1	35.8	11.1
Double vision	21.8	75.6	2.6
Itching	34.1	58.8	7.1
Floaters	44.8	50.8	4.5
Feeling of something in eye	37.9	55.8	6.2

A majority of patients reported an improvement in 5 of the 12 functional activities. The largest improvement was noted in reading words on television and driving at night, followed closely by reading telephone books and standard sized text. Most of those who did not indicate improvement in a given activity remained unchanged, but between 2 and 5 percent said that they got worse after the surgery.

Much the same pattern emerged for symptoms. Improvement was most striking for blurred vision, where over three quarters said they got better. A little over half reported less sensitivity to glare, and somewhat less than half indicated improvement with "floaters." While most of the rest remained unchanged, between 3 and 11 percent reported getting worse. Sensitivity to glare was the symptom most likely to worsen after surgery.

Patients may improve in some symptoms or functions and worsen in others. To get a sense of how symptoms and functional abilities changed overall, we divided our respondents into four groups:

- those reporting clear improvement (one or more items improved with none worsening),
- those that experienced no change (no items either improving or worsening),
- those reporting a clear deterioration (one or more items worsening with none improving), and
- those with mixed results (some items improved and others worsened).

The distribution for functions, symptoms, and functions and symptoms together is shown in table 3.3.

Table 3.3: Cumulative Change in Symptoms and Functions: Cataract Patients Who Experienced Improvement, No Change, Worsening, or Mixed Outcomes

	Cumulative change			
	Better	No change	Worse	Mixed
Functions	74 1%	9.7%	4.6%	11.7%
Symptoms	71.4	5.3	5.0	18.3
Functions and symptoms	65.9	1 7	2.4	30.0

The results are clearly favorable for a substantial majority of patients. In terms of change in visual functioning, symptoms, and both taken together, about three fourths to two thirds of the patients responding to our survey indicated some level of improvement with no offsetting worsening on another symptom or function. The next largest group, between 12 and 30 percent, improved in some areas and worsened in others. Uniformly adverse outcomes were limited to between 4 and 5 percent of patients for functions and symptoms and only a little more than 2 percent considering functions and symptoms together. Another 1.7 percent indicated no change for any symptoms or functions.

Interim Outcomes

Interim outcomes may seem less consequential because they are explicitly temporary. However, if the long-term gains in eyesight to be won are small, it may make a difference to patients how much discomfort and inconvenience they have to endure in order to achieve them. In this section, we look at the standard effects of any surgery (pain, swelling, and so on), plus temporary flare-ups in eye-specific symptoms, such as itchiness and floaters. We also examine the overall amount of time patients needed to return to a normal pattern of daily living after surgery as well as the incidence of complications (such as infections and the need for repeated procedures).

One basic issue about any outpatient procedure is whether patients are discharged before they are "ready," particularly in terms of recovery from the anesthesia. Therefore, we asked our respondents whether they had any of the following symptoms at discharge or immediately thereafter: nausea, pain, sleepiness, dizziness, or breathing problems. The large majority indicated that they either experienced them not at all or else only slightly (see table 3.4). However, 10 percent did report leaving the surgical clinic with moderate to severe pain or sleepiness—a somewhat notable result when 2 out of 3 patients undergoing the same procedure reported no pain or sleepiness. Taking all five symptoms into account, 22 percent of patients experienced at least one symptom to a moderate or severe degree compared to 42 percent reporting no symptoms at all and 36 percent experiencing one or more of the symptoms only slightly.

Table 3.4: Proportion of Patients Who Experienced Symptoms at Discherge or Immediately After

Symptom	None	Slight	Moderate	Severe
Nausea	89 4%	6.2%	2.3%	2.1%
Pain	66.2	23.4	8.5	2.0
Sleepiness	65.9	23 6	9.1	1.4
Dizziness	77 7	16.8	4 2	1.2
Breathing problems	92.6	4 6	1.9	0.9
Most severe response among five symptoms	41 7	36 2	16.3	5 8

Once past the initial point of discharge, certain symptoms typically accompany any surgery. We asked about numbness, pain or soreness, swelling, and bleeding (see table 3.5). Most patients said that they did not have these symptoms, although pain was relatively common, with about 11 percent indicating a moderate to severe level followed by 8 percent with swelling. About 17 percent had at least one of these symptoms to a moderate or severe degree. However, these symptoms rarely continued for very long (see table 3.6). Pain was the most enduring symptom, but only 5.5 percent reported it lasted more than 2 weeks.

Table 3.5: Proportion of Patients With Symptoms That Generally Accompany Surgery

Symptom	None	Slight	Moderate	Severe
Numbness	82.7%	12.5%	4.0%	0.8%
Pain	56.0	33.5	8.3	2.2
Swelling	73.1	18.5	7.0	1.4
Bleeding	93.2	5.9	0.7	0.3
Most severe response among four symptoms	43.6	39 1	13.6	3.7

Table 3.6: Proportion of Patients Who Experienced Various Durations of Symptoms That Generally Accompany Surgery

Symptom	None	1-2 days	3-14 days	2-4 weeks	1-2 months	More than 2 months
Numbness	84.9%	11.8%	1 9%	0.6%	0.2%	0.6%
Pain	58 8	24 3	11.3	2.1	1.9	1.5
Swelling	76.3	11.2	8.5	1.8	0.9	1.2
Bleeding	93.6	4.3	1.5	0 3	0	0.3
Longest duration of any of four symptoms	48.9	26.7	15.8	3.8	2.3	2.6

Beyond the general symptoms that accompany all surgery, one could expect a temporary increase in the symptoms specific to vision that we have already examined for long-term changes. These symptoms proved to be both more intense and longer lasting than those related to surgery in general (see tables 3.7 and 3.8). Most common was sensitivity to glare, which affected 26 percent moderately or severely. Overall, 13 percent of patients were bothered severely by at least one of these symptoms following surgery and another 24 percent were moderately bothered. They also persisted longer than the general surgery symptoms. Eighteen percent reported being troubled by glare more than 2 months after surgery, 11 percent by blurred vision and by floaters. Overall, 29 percent reported having at least one of these symptoms 2 months after the surgery.

Table 3.7: Proportion of Patients With Eye Symptoms Following Surgery

Symptom	Patient did not have symptom	Patient had symptom and was bothered			
		Not at all	Little	Moderately	Severely
Blurred vision	56.8%	9.7%	18.6%	10.0%	4.9%
Sensitivity to glare	31.4	13.2	29.0	18.3	8.1
Double vision	86.5	3.7	5.6	2.9	1.3
Itching	61.3	11.9	18.1	7.2	1.6
Floaters	59.0	16.0	17.3	6.3	1.4
Feeling of something in eye	53.8	12.5	22.9	8.3	2.6
Most severe response among six symptoms	14.8	16.0	32.5	24.1	12.6

Table 3.8: Proportion of Patients With Various Durations of Eye Symptoms Following Surgery

Symptom	None	1-2 days	3-14 days	2-4 weeks	1-2 months	More than 2 months
Blurred vision	60.7%	10.5%	10.9%	4.3%	3.0%	10.5%
Sensitivity to glare	38.7	13.4	18.7	7.7	3.9	17.7
Double vision	88.8	3.3	2.6	1.1	0.8	3.4
Itching	63.6	14.8	12.0	3.3	2.0	4.3
Floaters	63.1	8.4	9.1	4.6	3.4	11.4
Feeling of something in eye	58.9	12.8	12.3	5.3	3.0	7.7
Longest duration of any of six symptoms	21.1	15.3	18.5	10.6	5.5	28.9

These symptoms should also be assessed relative to the degree that patients were bothered by them prior to the surgery. As table 3.9 shows, for the group of patients as a whole, all the eye symptoms were substantially reduced relative to the period immediately prior to the cataract operation. Each continued to improve, so that the proportion of patients bothered either moderately or severely was still lower when the surveys were completed.

Table 3.9: Proportion of Patients Who Experienced Eye Symptoms Before Surgery, Following Surgery, and at Time of Survey

Symptom	Patient did not have symptom	Patient had symptom and was bothered			
		Not at all	A little	Moderately	Severely
Itching					
Before	55.0%	8.2%	20.2%	12.2%	4.4%
Following	61.3	11.9	18.1	7.2	1.6
At survey	75.6	6.8	13.5	3.4	0.7
Sensitivity to glare					
Before	23.4	6.0	25.4	26.3	18.8
Following	31.4	13.2	29.0	18.3	8.1
At survey	43.5	12.9	25.9	12.0	5.8
Blurred vision					
Before	12.0	5.2	23.7	31.7	27.4
Following	56.8	9.7	18.6	10.0	4.9
At survey	72.4	4.8	13.3	6.4	3.1
Double vision					
Before	75.5	3.2	9.9	7.7	3.8
Following	86.5	3.7	5.6	2.9	1.3
At survey	92.6	1.6	2.9	1.8	1.1
Floaters					
Before	40.3	15.4	24.1	14.4	5.7
Following	59.0	16.0	17.3	6.3	1.4
At survey	68.0	16.2	11.6	3.4	0.8
Feeling of some thing in eye					
Before	52.5	6.9	20.8	13.1	6.7
Following	53.8	12.5	22.9	8.3	2.6
At survey	77.3	7.1	11.2	3.5	0.9
Most severe among six symptoms					
Before	3.0	6.2	20.9	34.9	35.1
Following	14.8	16.0	32.5	24.1	12.6
At survey	29.3	16.8	29.2	16.9	7.8

Thus, there appears not to have been a substantial incidence of adverse interim outcomes reported by patients that involved either general symptoms of surgery or changes in eye-specific symptoms. However, a small number deviated substantially from this overall positive pattern.

For a more general measure of the cost of surgery, we asked our respondents how long it took them to begin to function normally and to get fully back to normal. Table 3.10 shows the considerable variation in recovery times reported by cataract patients. Although 61 percent had started to recover within a week, and had fully recovered within 2, nearly a quarter took more than a month to get fully back to normal and 9 percent more than 2 months.

Table 3.10: Proportion of Patients Who Reported They Needed Various Lengths of Time to Recover From Surgery

	Time needed to	
Length of time	Begin to function normally	Get fully back to normal
Less than 1 day	23.1%	13.5%
1-7 days	37.8	27.8
1-2 weeks	16.9	19.2
2-4 weeks	11.7	17.0
1-2 months	5.9	13.5
More than 2 months	4.6	9.0

Finally, we asked about a series of specific adverse events that can occur to patients on their way to full or partial recovery. Although they may be unavoidable in particular circumstances, these events are inherently negative outcomes; that is, they are not considered part of the normal course of treatment. They include episodes of infection, recurrence of the original problem, needing a second operation "related to this surgery," and hospitalization for complications of the surgery (see table 3.11). All these should be rare events but how rare may indicate the quality of care provided. For our respondents, the incidence of these events ranged from 13 percent having a second procedure to 1.5 percent hospitalized for complications.[1] Almost a fifth reported one of these events. There were no substantial differences in incidence across the states.

Table 3.11: Proportion of Patients With Various Adverse Events

Event	Percent
Infection	4.5%
Recurrence of problem	6.6
Second procedure	13.1
Hospitalization for complications of surgery	1.5
One or more of the four events	19.5

Conclusion

Overall, a large majority of patients perceived a clear benefit from their cataract surgeries. Our survey responses indicate that the intended benefits of cataract surgery are in fact reaching the general population served by the Medicare program. Still, the outcomes obtained from surgery varied among patients. While approximately two thirds of patients reported only positive changes in terms of symptoms and functions, most of the rest reported mixed results. Even for this second group the net change following cataract surgery might be positive but to a lesser extent than for others.

Such variations in outcomes can be used to explore possible areas for further improvement. For example, comparing patients who reported mixed results to similar patients with more uniformly favorable outcomes might help identify more effective practices and surgeons providing higher quality services. Analogous efforts could help find the reasons why some patients had severely adverse interim outcomes, such as pain and relatively long periods needed to return to normal functioning.

[1]Many of the second procedures were probably outpatient laser capsulotomies for posterior capsular opacification. This is a relatively frequent complication of cataract surgery, and the laser treatments are routinely used to treat the condition. It is even fairly common for patients to have a laser capsulotomy performed as a preventive measure. However, recently published research has shown that laser capsulotomies increase the risk of other complications, such as retinal detachment. See J.C. Javitt et al., "National Outcomes of Cataract Extraction: Increased Risk of Retinal Complications Associated With Nd:YAG Laser Capsulotomy," Ophthalmology, 99:10 (October 1992), 1487-98.

Chapter 4

The Effect of Presurgical Conditions on Outcomes of Cataract Surgery

The description of outcomes in chapter 3 considered the overall distribution of outcomes for the entire group of patients we surveyed. However, in examining outcomes (especially long-term changes in visual impairment and symptoms), it is important to take account of where people start from. This chapter compares outcomes for patients who reported having moderate or severe problems prior to surgery with outcomes for patients who reported having no more than slight problems before they had their cataract surgery.

Change in Individual Symptoms and Functional Impairments

Tables 4.1 and 4.2 show the proportion of patients reporting that their symptoms and functional capabilities improved, stayed the same, or got worse. For each symptom and function, we compare the results of patients who crossed the threshold for the restrictive criterion in chapter 2 (moderate or severe problems for symptoms or functions prior to surgery) to those who did not. Change in this analysis represents any increase or decrease in the extent to which the patient was bothered by a symptom or had difficulty with a functional activity.

Table 4.1: Proportion of Patients Who Reported Their Visual Functioning Improved, Stayed the Same, or Worsened by Difficulty Experienced Before Surgery

		Change after surgery		
Activity	Difficulty before surgery	Better	Same	Worse
Watching TV				
Seeing picture at all	Moderate to great	89.5%	9.4%	1.1%
	Little or no	23.2	73.1	3.7
Seeing colors	Moderate to great	91.4	7.8	0.8
	Little or no	16.9	80.1	3.0
Recognizing people	Moderate to great	87.5	10.2	2.3
	Little or no	27.4	68.3	4.2
Reading words on screen	Moderate to great	87.4	10.9	1.7
	Little or no	36.3	56.5	7.2
Reading				
Headlines	Moderate to great	89.0	9.6	1.4
	Little or no	17.2	80.3	2.5
Large print	Moderate to great	84.6	13.0	2.4
	Little or no	14.6	83.5	2.0
Standard text	Moderate to great	86.2	12.5	1.3
	Little or no	35.4	56.4	8.3
Telephone books	Moderate to great	78.5	19.6	1.9
	Little or no	34.9	57.3	7.8
Driving				
Short distances daytime	Moderate to great	95.5	4.5	0
	Little or no	22.7	75.2	2.1
Long distances daytime	Moderate to great	90.6	8.9	0.5
	Little or no	30.7	63.9	5.5
Short distances night	Moderate to great	84.7	14.4	1.0
	Little or no	39.8	52.8	7.5
Long distances night	Moderate to great	74.8	24.3	0.9
	Little or no	34.9	57.7	7.4

Table 4.2: Proportion of Patients Who Reported Their Eye Symptoms Improved, Stayed the Same, or Worsened by Condition Before Surgery

		Change after surgery		
Symptom	Condition before surgery	Better	Same	Worse
Blurred vision	Moderate to severe	91.4%	7.4%	1.2%
	Little or none	58.0	35.4	6.5
Sensitivity to glare	Moderate to severe	78.8	19.0	2.2
	Little or none	31.5	49.9	18.6
Double vision	Moderate to severe	89.2	10.1	0.6
	Little or none	13.2	84.0	2.8
Itching	Moderate to severe	89.6	8.7	1.7
	Little or none	23.3	68.6	8.1
Floaters	Moderate to severe	91.8	7.4	0.7
	Little or none	32.8	61.8	5.4
Feeling of something in eye	Moderate to severe	88.8	10.5	0.7
	Little or none	25.5	66.9	7.6

As might be expected, patients who reported having moderate or severe visual impairment prior to surgery were much more likely to report an improvement after surgery than those who reported having no impairment or slight impairment. For each of the 12 activities, large majorities in the former category reported improvement afterward (a range of 75 to 96 percent), compared to a minority of those having little or no difficulty presurgery (15 to 36 percent). Most of the group without substantial impairment prior to surgery experienced no change.

The same pattern emerged for five of the six symptoms. For all except blurred vision, large majorities (79 to 92 percent) of those who indicated moderate to severe problems before surgery reported improvement, compared to a minority (13 to 33 percent) of those with no more than slight problems prior to surgery. Blurred vision was the one symptom in which a majority of both groups said that they got better, though still a much larger proportion among those with moderate to severe problems prior to surgery—91 versus 58 percent.

The pattern observed in both tables, then, is that those who started out worse off were more likely to report improvement than those with few initial problems. Our data indicate the extent to which this pattern holds true for our samples of cataract patients. More importantly, however, the reports from the patients show that the likelihood of an adverse outcome (that is, the patient's getting worse after the surgery) follows the same logic. That is, the numbers of patients who reported being worse after the procedure was consistently higher among those who reported having few problems prior to surgery.[1] This demonstrates that the risks that argue against surgery in the absence of actual visual impairment are not solely hypothetical.

Change in Overall Symptoms and Functional Impairment

Table 4.3 shows what happens when the focus shifts from the individual functional activities and symptoms to cumulative change across functions and symptoms. It compares the patients who did or did not meet the more restrictive threshold in terms of the proportion that fell into the four categories of reported change outlined in chapter 3: change uniformly for the better, no change at all, change uniformly for the worse, and a mixture of favorable and adverse change. The table presents these results first for functional impairments, then for symptoms, and finally for both functions and symptoms together.

Table 4.3: Cumulative Change in Symptoms and Functions: Percent of Cataract Patients Who Experienced Improvement, No Change, Worsening, or Mixed Outcomes by Condition Before Surgery

		Change after surgery			
	Condition before surgery[a]	Better	Same	Worse	Mixed
Functions	Moderate to severe	81.4%	2.3%	3.5%	12.8%
	Little or none	50.9	33.0	7.8	8.3
Symptoms	Moderate to severe	77 1	1.8	2.9	18.2
	Little or none	58.3	13.4	9.8	18 6
Functions and symptoms	Moderate to severe	67 6	0	1.8	30.6
	Little or none	57 0	10 6	5 1	27 2

[a]The highest level of difficulty or problem reported by the patient for any functional activities or symptoms (as relevant) before surgery

These figures reveal several broad patterns. First, half or more of each group reported a uniformly positive change for functions and symptoms, both separately and together. By contrast, fewer than 10 percent of either group reported uniformly negative changes following surgery. As with the analysis of individual functional impairments and symptoms, the patients who had moderate to severe problems before surgery were more likely to report positive changes and less likely to report negative ones. However, the difference between the two groups narrows as the focus shifts from the individual items to functions and symptoms overall and then both taken together. It is also apparent that mixed outcomes—in which a

[1]The single exception among the six symptoms and 12 functional activities was reading large print, where patients with substantial problems prior to surgery were slightly more likely to get worse (2 4 versus 2.0 percent).

patient reports that some functional impairments or symptoms improved and others worsened—are fairly common for both groups of patients, especially when the full range of functional activities and symptoms is considered.

These overall patterns were replicated in the four states, with generally minor variations. The largest discrepancy occurred in the area of functional limitations, where 62 percent of the patients in Texas with no more than minor symptoms or functional impairments prior to surgery had uniformly better outcomes compared to a range of 44 to 53 percent in the three other states. A correspondingly lower percentage of these patients remained unchanged in Texas compared to the rest. However, the difference was not statistically significant, reflecting the relatively small number of cases in this category.

The analysis so far has looked only at the direction of change and not at its magnitude. To see how the amount of favorable and adverse change varied between patients who did or did not report substantial problems prior to surgery, we examined the number of dimensions in which these changes took place. That is, we determined the number of individual functions and symptoms that each patient reported had improved and the number that got worse. For functions this could range from 0 to 12, for symptoms from 0 to 6. The distribution of these results across both sets of patients are presented in tables 4.4 to 4.7.

Table 4.4: Number of Functions That Patients Reported Improved Following Surgery by Whether Patients Reported Having Substantial or Minor Problems Before Surgery

Number of functions reported to improve	Patients reporting substantial problems before surgery	Patients reporting only minor problems before surgery
0	8.3%	44.9%
1	10.2	21.2
2	10.6	9.7
3	12.0	10.2
4	9.9	3.8
5	10.1	5.5
6	10.6	2.1
7	9.6	1.3
8	7.9	0.8
9	3.4	0
10	3.4	0.4
11	2.7	0
12	1.2	0

Table 4.5: Number of Functions That Patients Reported Got Worse Following Surgery by Whether Patients Reported Having Substantial or Minor Problems Before Surgery

Number of functions reported to worsen	Patients reporting substantial problems before surgery	Patients reporting only minor problems before surgery
0	83.7%	83.9%
1	8.8	8.9
2	3.6	3.0
3	1.5	2.5
4	1.2	0.8
5	0.6	0.4
6	0	0
7	0.3	0.4
8	0.2	0

Table 4.6: Number of Symptoms That Patients Reported Improved Following Surgery by Whether Patients Reported Having Substantial or Minor Problems Before Surgery

Number of symptoms reported to improve	Patients reporting substantial problems before surgery	Patients reporting only minor problems before surgery
0	7.4%	24.1%
1	16.9	36.3
2	21.8	19.8
3	20.5	10.5
4	15.5	5.9
5	11.9	3.4
6	5.9	0

Table 4.7: Number of Symptoms That Patients Reported Got Worse Following Surgery by Whether Patients Reported Having Substantial or Minor Problems Before Surgery

Number of symptoms reported to worsen	Patients reporting substantial problems before surgery	Patients reporting only minor problems before surgery
0	76.5%	77.6%
1	16.6	16.0
2	4.4	3.4
3	1.8	2.5
4	0.4	0.4
5	0.2	0
6	0.1	0

Thus, the patients who started with a higher level of functional and symptomatic problems prior to surgery tended to perceive improvement in a larger number of areas than patients who had no more than slight problems prior to surgery. The former group of patients reported a median of 4 functions and 3 symptoms that got better, while patients without substantial visual problems prior to surgery reported a median of 1 for both functions and symptoms. However, the two groups of patients reported almost identical distributions for the number of functions and symptoms that deteriorated, with the large majority (83.7 to 83.9 percent for functions and 76.5 to 77.6 percent for symptoms) indicating that none had changed for the worse.

Summary

Clearly, the patients who had substantial functional difficulties or symptoms prior to surgery generally experienced greater improvement in those conditions than patients who started out with fewer problems. At the same time, it is notable how consistent even that second group of patients was in reporting positive outcomes from the surgery. Evidently, their physicians were highly successful in preventing adverse developments across the full range of symptoms and functions, while achieving consistent, if necessarily small, improvements in areas where these patients had experienced minor problems. Most commonly, this involved the elimination of slight problems with blurred vision.[2]

In sum, we found that a patient's condition prior to surgery was related to the long-term outcomes that he or she could expect from the procedure. For specific functional limitations and symptoms, patients who reported substantial problems before surgery were most likely to indicate a more favorable status afterward. Looking broadly at functional impairments and symptoms overall, the two groups of patients were more comparable. Most reported uniformly positive changes, while a substantial minority indicated mixed outcomes and a few described uniformly negative results. In this case, the main difference between patients who had substantial presurgical problems and those who did not was in the number of functions and symptoms that they reported got better after surgery.

[2]Sixty-three percent of this group reported some blurred vision prior to surgery (although it bothered them no more than slightly), and 91 percent of them experienced improvement after surgery.

Appendix I

Interpreting Survey Data on Patients' Experiences Before and After Surgery

In using surveys to collect data on patients' experiences, it is important to address factors that might affect the ability of a specific survey instrument to produce accurate information about a patient's condition both before and after the surgery. What follows is a discussion of several such issues. These include the content and wording of survey questions and the potential for biased results arising from any systematic differences between respondents and nonrespondents, problems in recall, or variations among respondents in their willingness to report certain events or perceptions.

Content of the Survey Instrument

The value of any survey instrument fundamentally depends on the specific content of the questions it contains. There are two major concerns. First, validity: Have the subjects of interest been fully addressed? Second, reliability: Are the questions worded so that the respondents interpret them as intended? In developing our instrument, we took a number of steps to deal with both these concerns.

To make sure we addressed the right topics, we consulted both physicians and patients involved in outpatient cataract surgery. We queried a number of surgeons about relevant symptoms and complications for cataract surgery. Then we organized a series of focus groups with patients to get a detailed sense of how their cataract had affected their eyesight and daily activities before the operation, what they experienced during convalescence, and how their vision had changed since the surgery. The core questions of our survey relating to eye symptoms and visual functioning before and after the surgery were based on both sets of discussions.

We drew on the focus groups as well to ensure that our questions were worded in ways that made sense to patients. For more general questions on overall health and physical functioning, we adopted items from the "MOS 36-Item Short-form General Health Survey," a frequently used and well-tested instrument.[1] Then, once our survey was drafted, we conducted pretests with additional cataract patients to uncover any remaining ambiguities in the wording of the questions.

For a final check, we sent the questionnaire to a sample of 144 Medicare outpatient eye surgery patients from Pennsylvania. Factor analyses and

[1]John Ware and Cathy Sherbourne, "The MOS 36-Item Short-form Health Survey," Medical Care, 30:6 (June 1992), 473-81

reliability tests of the responses showed that they clustered in patterns that were consistent with the substantive content of the questions.

Differences Between Respondents and Nonrespondents

The 76 percent response rate for the survey minimizes the possibility that our results are biased by any differences between respondents and nonrespondents. Moreover, comparing respondents to nonrespondents by state, age, sex, and race (the personal characteristics for which information on both respondents and nonrespondents was available from HCFA), we found little difference between the two groups except for race. Thus, 77 percent of male cataract patients responded to the survey as did 76 percent of the females. Response rates from the four states varied from a high of 79 percent in Pennsylvania to a low of 72 percent in California. Even across different age groups, the response rates are surprisingly uniform. The lowest response rate, 54 percent, came from the small under-65 group (2.3 percent of the total), composed largely of disabled people. For all others, the response rate declined slowly from 79 percent for the 65- to 70-year-old group to 72 percent for those 90 years old or older. These response rates from the older age groups are particularly striking given that nonresponse includes any who had died or become mentally infirm.

The most notable difference between respondents and nonrespondents appeared on the dimension of race. Unfortunately, HCFA's data only distinguish between whites and blacks, plus an "other" category that presumably includes Asians and some, but not all, Hispanics.[2] Whites responded to our cataract survey at a rate of 77 percent, compared to 62 percent for both blacks and "other." While these differences are important, their effect on the representativeness of the respondents for the overall sample is limited by the small number of nonwhites in the original universe. Blacks, for example, constituted just 4.8 percent of those identified by the PROs as having received cataract surgery, and "others" even less, 3.2 percent. Thus, with a still reasonably high response rate of 62 percent, both nonwhite groups are only slightly underrepresented in the group of respondents. Our respondents are 3.9 percent black (compared to 4.8 in the original sample) and "other" are 2.6 percent (compared to 3.2).

[2]In responding to the 1990 U.S. census, which asked separately about race and Hispanic origin, 51.7 percent of Hispanics identified themselves as white, 3.4 percent as black, and 42.8 percent as "other."

Potential Errors in Recall

Another potential concern with our survey data is that patients may have trouble remembering how well they could see and function some time in the past. Survey research has documented the difficulty that respondents can have in accurately recalling past events or attitudes. It seems likely that memories would fade about prior visual impairments as well, particularly for those who responded to our survey months after the surgery was performed.[3] However, there are a number of reasons to expect recall to pose less of a problem in this instance than is often the case for survey research.

First, the question of how well one sees after a cataract operation, compared to before it was performed, is a highly salient question to anyone who has undergone the procedure. The importance of this question to the respondents personally means that their interest in how they saw prior to the surgery is likely to be strong. Moreover, the type of information we ask for concerns patient experiences directly over an extended period of time. By contrast, prior research has demonstrated problems in recalling quite different kinds of information, such as the number and timing of particular events that occurred. Further, there is no stigma attached to the information we sought and therefore more or less unconscious distortion may not be as likely as with more sensitive topics. Of course none of these factors guarantees accuracy, but together they should decrease the likelihood of distortion for at least some aspects of recall.

In addition, the slowness with which cataracts often develop means that patients' assessments of their own visual impairments prior to the surgery may be better grounded after the surgery than before it. It is only after the cataract has been removed and recovery from the surgery largely complete that the patient can experience what he or she had been missing visually beforehand. This general phenomenon is known as a "response shift." It occurs when the intervention of interest (in this case, the cataract surgery) affects the frame of reference employed by the respondent to assess a change. In this circumstance, methodologists have concluded that it is more valid to use assessments of the preintervention situation made after the intervention has taken place.[4]

[3]The median time between the operation and completion of the survey was 7.3 months. The shortest interval was 4.8 months. Fewer than 7 percent of the respondents had been operated on more than 10 months previously. Normally it takes about 3 months for a patient's eyesight to stabilize after cataract surgery

[4]See James R. Terborg and Gregory A. Davis, "Evaluation of a New Method for Assessing Change to Planned Job Redesign as Applied to Hackman and Oldham's Job Characteristic Model," Organizational Behavior and Human Performance, 29 (1982), 112-28.

As we were developing our questionnaire, we conducted a small-scale pilot study that produced results consistent with the concept of response shift. Working through local area physicians, we recruited 16 patients to complete a questionnaire just prior to their cataract surgery, including questions about eye function (reading, watching TV, and driving). Several months later we followed up with a second questionnaire that asked about the same topics, both then (after surgery) and before. Comparing the two sets of "presurgery" responses (contemporaneous and recalled), we found that for 11 of 12 functional items, the 15 patients who responded to both questionnaires rated their presurgery eyesight worse after the surgery than they had before. The small size of the patient sample meant that only 2 of these 12 comparisons were statistically significant. However, the consistency of these results across items lends support to the expectation that a response shift would occur with cataract surgery. (No such pattern was found for other items not related to visual functioning.) Therefore, we concluded that the use of patient assessments of presurgical visual impairments collected after the surgery has occurred is not only legitimate but preferred, to improve accuracy, despite the somewhat greater risk of blurred recall.

Possible Bias in Patient Responses

Patient-reported information is relatively subjective and variable, compared to physicians' observations based on physical examinations and diagnostic test results. Consequently, patients can describe similar circumstances or situations quite differently. For example, some are likely to be more sensitive to pain or to glare than others. However, since information about outcomes is often lacking in the facility medical records currently reviewed for outpatient surgery, patient-reported data may provide the most feasible alternative source of information for judging the effect of the care provided. Also, to the extent that patients' perceptions themselves are of interest, this variation among individuals is not a source of error but is, rather, part of the phenomenon being measured.

However, patients may vary as well in their willingness to aeknowledge the perceptions that they have. Some may, for example, prefer to minimize any problems they experience while others find solace in recounting every difficulty. We expect that this kind of response bias had some effect on the individual responses recorded in our survey.

Because we analyzed these data collectively, rather than case by case, these biases in individual responses should have diminished effect. As the number of cases analyzed increases, such differences across individuals (for example, minimizing or exaggerating pain) will tend to cancel each other out. Nevertheless, the possibility remains in any given analysis that biases in one direction may outweigh biases in another.

Appendix II

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APPROPRIATE CARE FOR CATARACT SURGERY PATIENTS BEFORE AND AFTER SURGERY

Issues of Medical Safety and Appropriateness

Staff Paper
prepared by the

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SUMMARY

In 1976, a study by the U.S. Department of Health, Education, and Welfare addressed the issue of what services to cataract patients were appropriately provided by optometrists (U.S. DHEW, 1976). This OTA Staff Paper, prepared at the request of the Subcommittee on Health of the House Committee on Ways and Means, reconsiders some aspects of that topic in light of some technological changes, legal changes, and other changes that have occurred in cataract surgery during the past decade.

Traditionally, the ophthalmologist who performs cataract surgery on a patient is responsible not only for the surgery itself but for a preoperative assessment to evaluate the patient's fitness for surgery and for postoperative care during the healing process.[1] In the past several years, the traditional model of perioperative care for cataract surgery patients has been challenged as a consequence of changes in technology and legal and other changes in Medicare coverage and reimbursement.

- Changes in surgical techniques have reduced the risks of cataract surgery, and more than 90 percent of cataract surgery patients now have cataract surgery in outpatient settings rather than in the hospital.[2] For patients who now have cataract surgery in outpatient settings such as hospital outpatient departments, surgicenters, or private offices, postoperative care that would once have been

1As normally defined, preoperative care is the process of examining and performing diagnostic tests on a patient to assess a patient's fitness for surgery. Postoperative care, which begins with completion of a surgical procedure and continues until the patient's wound has healed, is the process of patient management following surgery that is necessary to ensure the best possible surgical outcome. Throughout this Staff Paper, OTA uses the terms preoperative care and postoperative care specifically in these ways to refer to care before and after cataract surgery. Perioperative care encompasses both preoperative and postoperative care.
2Currently, 95 percent of Medicare cataract surgery is done in outpatient settings (Ahern, 1988).

given to them by their ophthalmic surgeon while they were recovering from surgery in the hospital can now be given in outpatient settings.

- Two Federal laws have changed the definition of "physician" in the Social Security Act to expand the range of services that optometrists can receive reimbursement for under Medicare. Section 937 of the Omnibus Budget Reconciliation Act of 1980 (OBRA-80, Public Law 96-499) changed the definition to allow optometrists to be reimbursed by Medicare for any Medicare-covered service related to the condition of aphakia[3] providing that the performance of that service by optometrists was authorized by the State in which the optometrist practiced. Section 933 of the Omnibus Budget Reconciliation Act of 1986 (OBRA-86, Public Law 99-509) changed the definition to allow optometrists to be reimbursed for all Medicare-covered services that optometrists are authorized to perform by the State in which the optometrist practices.[4] Under OBRA-80 and even more under OBRA-86, optometrists in some States began billing Medicare carriers for postoperative services related to cataract surgery (Mitchell, 1988).
- Since 1986, the Health Care Financing Administration (HCFA) has issued several sets of instructions to Medicare carriers that have been interpreted as sanctioning Medicare payment to optometrists for postoperative services related to cataract

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3Aphakia, the absence of the natural crystalline lens of the eye, is a condition that may be present from birth or be caused by surgical removal of the lens (e.g., in the course of cataract surgery). A person who has just had cataract surgery and is in the unstable postoperative period is technically aphakic, although many would argue that such a patient is receiving services for cataract rather than aphakia.

4A survey of State laws pertaining to the practice of optometry is available from the American Optometric Association (American Optometric Association, November 1987). Most State optometry laws do not specifically authorize or prohibit the provision of "preoperative or postoperative care related to cataract surgery"; rather, each law specifically allows or prohibits various drugs and procedures that might be employed in such care.

surgery. Medicare carriers generally pay a "global fee" for cataract or other surgery. A global fee typically covers the presurgical evaluation of the patient, the surgery itself, and the postoperative followup visits. HCFA has established a billing procedure that some carriers have used to allow the splitting of a global fee between an ophthalmologist who provides cataract surgery and an optometrist who provides followup care (Mitchell, 1988).

The tradition that a surgeon is responsible for the preoperative and postoperative care of a surgical patient has a long history in medicine. According to the principles of the American College of Surgeons: "The responsibility of a surgeon includes preoperative diagnosis and care, the selection and performance of the operation, and postoperative surgical care" (Am. College of Surgeons, 1985). This OTA Staff Paper considers the medical safety and appropriateness of arrangements under which an ophthalmologist performs cataract surgery on a patient and an optometrist at a site separate from the ophthalmologist provides either the preoperative visit to evaluate a patient's fitness for surgery or several of a patient's postoperative visits.

OTA found no scientific studies of patient outcomes when optometrists provide preoperative or postoperative care for cataract surgery patients. Consequently, direct comparisons between the quality of perioperative care provided by ophthalmologists and optometrists could not be made.

In the absence of scientific studies of the outcomes associated with alterations in the traditional model of perioperative care for cataract surgery patients, conclusions about the medical wisdom of giving optometrists an expanded role in the provision of preoperative or postoperative care for cataract surgery patients have to be based on considerations of:

1. the nature of possible postoperative complications after cataract surgery and the skills that may be needed to help prevent or manage those complications,
2. differences in the education and training of optometrists and ophthalmologists that might affect the quality of care the two types of professionals are able provide to cataract surgery patients in the perioperative period,[5] and
3. general models for the provision of postoperative care by someone other than the attending surgeon.

Cataract surgery patients may develop any of several types of postoperative complications. Some of the more common ocular complications can interfere with vision but do not have to be dealt with immediately. On the other hand, there do exist a few rare ocular complications (e.g., endophthalmitis,[6] expulsive intraocular hemorrhage, severe wound rupture) that have to be dealt with immediately to prevent the loss of an eye. A number of other ocular complications are not emergencies like these but are very serious and can destroy an eye if not properly managed (e.g., corneal edema, secondary glaucoma, detached retina) (Jaffe, 1984). Systemic complications following cataract surgery are rare but do occasionally arise, especially in patients with pre-existing diseases such as diabetes or hypertension. Given the volume of cataract surgery performed, more than one million procedures per year, even a relatively small percentage of complications could reflect thousands or tens of thousands of patients.

5A recent OTA report on indicators of the quality of medical care found that physicians practicing in the area of their training are likely to deliver higher quality care than others (U.S. Congress, OTA, 1988). The same report found that malpractice compensation was not a reliable or valid indicator of quality.

6Endophthalmitis is a severe, sometimes painless, intraocular infection that may be caused by any of a variety of bacterial and fungal agents. The infection may cause a violent inflammatory reaction in the eye and can produce loss of vision if emergency treatment with systemic antibiotics, surgery, or other means is not initiated at once (Deutsch and Goldberg, 1984; Mauriello et al., 1983; Jaffe, 1984).

To minimize the likelihood that serious ocular or systemic complications will occur or become unmanageable requires good preoperative and postoperative care. In the preoperative period, a patient must be evaluated to determine whether cataract surgery is a justifiable risk given the state of the patient's cataract, health of the patient's eyes, and the patient's overall health; which cataract extraction procedure to use and whether to implant an intraocular lens (IOL); and whether the surgery should be done in the hospital or can safely be done in an outpatient setting. Such judgments should be based in part on knowledge of how concurrent eye or systemic disease affects the risks and potential complications of cataract surgery, as well as familiarity with various surgical techniques and IOLs.

In the postoperative period, a cataract surgery patient should be monitored for the development of any ocular or systemic complications. Some of the ocular complications associated with cataract surgery occur in the general population, but others occur primarily as complications of cataract or other surgery. A person who has been trained to perform eye surgery and has had clinical training in the postoperative management of eye surgery patients would probably be better able to recognize such complications than an individual without such training. Furthermore, a number of postoperative ocular complications in cataract surgery patients are associated with certain types of surgical procedures or IOLs or with certain types of problems during surgery. The surgeon who operates on a patient might be more alert to the possibility of these types of complications than someone who is not familiar with the specific procedure the patient underwent or was not present during surgery.

In almost all instances, the management of the ocular complications that arise after cataract surgery requires difficult judgments about whether and when to use a wide assortment of

medical and/or surgical procedures (Jaffe, 1984). The treatment of endophthalmitis and numerous other ocular complications requires the use of antibiotics, steroids, and/or other systemic medications that have to be prescribed by a physician (Jaffe, 1984).[7] The treatment of an expulsive hemorrhage, a detached retina, and several other ocular complications involves major eye surgery that only an ophthalmologist is trained to perform. The management of endocrinologic, cardiac, or other systemic complications may necessitate the involvement of an internist, cardiologist, or other physician.

The education and training of ophthalmologists differ in several important respects from the education and training of optometrists. Ophthalmology is a surgical specialty of medicine, and ophthalmologists must spend 4 years in medical school, 1 year as an intern in a hospital, and 3 years as a hospital-based ophthalmology resident. Optometry is not a specialty of medicine, and optometrists undergo a 4-year professional training program.

As a physician, an ophthalmologist gets 3 years of clinical training (2 years as a medical student and 1 year as a hospital intern) in the evaluation and treatment of patients with a variety of medical conditions. This experience may enable an ophthalmologist to evaluate a patient's fitness for surgery, taking into account the patient's systemic conditions. This experience may also enable an ophthalmologist to initiate management of postoperative complications that require certain systemic drugs or surgery. At no point during training does an optometrist receive clinical training in the evaluation and treatment of patients with a range of medical problems.

7Most States permit optometrists to use certain drugs, under certain conditions, to diagnose eye disease, and 23 State laws permit optometrists to use certain drugs, under certain conditions, to treat selected eye problems (Hibbs, 1987; Mays, July 8, 1988). In no States, however, are optometrists licensed to use the full range of drugs that might be needed to manage the various complications of cataract surgery.

As an ophthalmology resident, an ophthalmologist gets 3 years of clinical training in the evaluation and treatment of patients with serious eye problems. An optometrist gets clinical training in the evaluation of patients for refraction but significantly less experience in the management of patients with serious eye problems. Finally, an ophthalmology resident performs cataract and other eye surgery and manages the postoperative care of many of the patients on whom he or she operates. An optometrist gets considerably less clinical exposure to patients who have undergone eye surgery.

Given the differences in training of ophthalmologists and optometrists just mentioned, it is the assessment of OTA that a preoperative evaluation to assess a cataract patient's fitness for cataract surgery must be done by the ophthalmologist who is to perform the surgery. The preoperative evaluation by an ophthalmologist should take into account not only the state of the cataract and general health of the patient's eye but any systemic problems the patient has that could affect risks and benefits of surgery. The information that is gathered during during a preoperative evaluation can affect the preoperative and postoperative management of a patient and the eventual outcome of the surgery itself.

A greatly expanded role for optometrists in the provision of postoperative care for cataract surgery patients--especially if the care is provided at sites that are geographically separate from the attending ophthalmologist--would represent a significant departure from the traditional model of care for such patients. Though the risks of an expanded role for optometrists have not been measured, several potential risks can be hypothesized:

1. If an optometrist or other caregiver who is not familiar with the specifics of a particular patient's cataract surgery provides postoperative care, continuity of care and the resulting quality of care may be adversely affected.

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2. Optometric training may not give optometrists sufficient clinical exposure to the postoperative management of cataract surgery patients to enable them to make physical exams consistent with those of an attending ophthalmologist or to fit their exams into a regimen of postoperative patient management.
3. If a cataract surgery patient develops an ocular complication that requires the involvement of the attending ophthalmologist (e.g., to prescribe drugs that have to be prescribed by a physician or to perform further eye surgery), a delay of several hours may occur before appropriate treatment is initiated, because few optometrists have 24-hour, weekend, on-call, or emergency services for their patients. In some cases (e.g., those involving endophthalmitis, expulsive hemorrhage), a delay of several hours could result in the loss of an eye or other serious problems.

In spite of the absence of a known risk, cautious medical practice suggests we should be aware of the potential risks of giving optometrists an expanded role in providing postoperative care for cataract surgery patients and make reasonable efforts to address the concerns that have been raised. Moving away from the traditional model of care without a scientific assessment of the likely effects on patient outcomes runs the risk of reducing the quality of care that cataract surgery patients receive. A more prudent approach would be to allow cautious alterations in the traditional model--alterations that attempt to address plausible hypothesized concerns about quality--and then to evaluate the effects.

INTRODUCTION

Cataract surgery is one of the most common procedures performed on the Medicare population. Traditionally, the attending surgeon--an ophthalmologist--is responsible for performing a preoperative evaluation of a patient's fitness for cataract surgery, for performing the cataract surgery, and for managing a surgical patient's postoperative care (Jaffe, 1984). In the last several years, the nature of cataract surgery itself has changed, and legal and other changes in Medicare payment have led some optometrists and ophthalmologists to challenge the traditional model of perioperative care for cataract surgery patients. This OTA Staff Paper evaluates the medical safety and appropriateness of an expanded role for optometrists in the preoperative and postoperative management of cataract surgery patients. OTA was asked to prepare the Staff Paper by the Subcommittee on Health of the House Committee on Ways and Means.

In a sense, this OTA Staff Paper is an update of a 1976 study conducted for Congress by the U.S. Department of Health, Education, and Welfare (HEW)[8] (see app. A for a summary). The question examined in the 1976 study was: What services related to aphakic and cataract conditions that are reimbursable under Part B of Medicare when provided by a physician (e.g., an ophthalmologist) are appropriate for reimbursement when provided by an optometrist (U.S. DHEW, 1976). The findings of the 1976 study, though comprehensive for the time, do not address several issues pertaining to medical safety and appropriateness of optometric involvement in perioperative care for cataract surgery patients as might be contemplated in 1988.

8In 1979, the Department of Health, Education, and Welfare (HEW) was separated into two components: the U.S. Department of Health and Human Services and the U.S. Department of Education.

One of the conclusions of the 1976 study was that optometrists were qualified to provide a broad range of services beyond refraction and the provision of eyeglasses (U.S. DHEW, 1976). According to the 1976 study, the initial diagnostic visit and any visits for cataract care before surgical intervention is suggested were within the competence of an optometrist. Such visits do not constitute preoperative care as traditionally defined to include the evaluation of a patient's fitness for surgery.

Not surprisingly, the 1976 study drew no specific conclusions with respect to the appropriateness of expanding optometric involvement in the postoperative care of cataract surgery patients. In 1976, unlike today, cataract surgery was a surgical procedure that was virtually always performed in the hospital. Optometric involvement in postoperative care for cataract surgery patients in the hospital would have run counter to all legal and hospital regulations and was therefore not even discussed in the 1976 report.

In its recommendations pertaining to the extension of Medicare Part B reimbursement to optometrists, HEW distinguished between services for aphakia and services for cataract conditions.[9] HEW recommended the extension of Part B Medicare reimbursement to optometrists for services related to aphakia that were authorized by State optometric scope of practice laws[10] and against the extension of Part B reimbursement coverage for Medicare-covered services provided by optometrists to cataract patients prior to surgery. The extension of

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9Aphakia, the absence of the natural lens of the eye, is a condition that may be caused by surgical removal of the lens in the course of cataract surgery. Whether a person who has just had cataract surgery and is in the immediate, unstable postoperative period remains a "cataract patient" or, having had the lens removed, is now an "aphakia patient" is a matter of opinion.

10HEW's recommendation with respect to extending Medicare Part B reimbursement to optometrists' services for aphakia was incorporated in Section 937 of the Omnibus Budget Reconciliation Act of 1980 (Public Law 96-499, OBRA-80), discussed later in this Staff Paper.

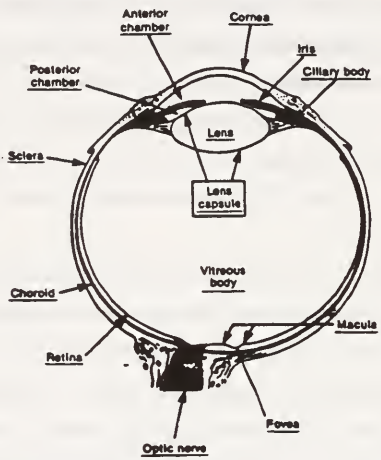
reimbursement for optometrists' services provided prior to cataract surgery, HEW said, should await resolution of issues that were not addressed by the 1976 study (e.g., development of an operational definition of cataract, patient health care implications, cost implications, delivery pattern changes, appropriate patient cost sharing).

Since the time of the HEW study, there have occurred technical, legal, and regulatory changes that, according to some observers, argue for an expansion in the traditional role of optometrists in the perioperative care of cataract surgery patients. The medical safety and appropriateness of moving away from the traditional model of perioperative care for cataract surgery patients is addressed in the discussion that follows.

CATARACTS: CAUSES AND PREVALENCE

A cross section of a normal human eye is depicted in figure 1. In a normal eye, a clear crystalline lens behind the pupil serves to focus light on the retina, which will ultimately receive the image and transmit it to the brain. The natural lens of an adult eye is about 10 mm (.39

Figure 1.—The Human Eye



inches) in diameter and approximately 4 mm thick. It is enclosed by a transparent membrane called a lens capsule that is 11 to 18 microns (0.0004 to 0.0007 inches) thick (Bloom and Fawcett, 1975). An opacity of the normally clear lens or of the lens capsule that encases the lens is known as a cataract. Typically, a cataract develops over time. As a cataract "matures" (progressively becomes more opaque), a person experiences a slow progressive loss of vision.

Cataracts are a major cause of visual impairment (trouble seeing even with glasses) in the U.S. population. According to data from the National Society To Prevent Blindness[11] cited by the Cataract Panel of the National Eye Advisory Panel, 35 percent of existing visual impairments and 53 percent of new cases of visual impairments are due to cataracts[12] (U.S. DHHS, PHS, 1987). Untreated, cataracts progress to the point where they cause blindness (Jaffe, 1984). Cataracts are the third leading cause of legal blindness in the United States (U.S. DHHS, PHS, 1987).

By far the most common type of cataract is senile (or senescent) cataract (U.S. DHHS, PHS, 1987). Senile cataracts are thought to be caused by alterations in the lens that are associated with increasing age (Jaffe, 1984). Other causes of cataract include diabetes mellitus and other metabolic disorders, toxic environmental agents such as radiation, trauma, infection, and congenital malformation (U.S DHHS, PHS, 1987).

Table 1 shows data on the prevalence of cataracts from the 1975 Framingham eye study (U.S. DHHS, PHS, 1987) and from the 1982 National Health Interview Survey conducted by the National Center for Health Statistics (LaPlante, in press). Although the data from the 1975 Framingham eye study are somewhat old, they do show the prevalence of cataract for the population over age 65. More recent data from the National Health Interview Survey show similar prevalence rates.

11The data from the Society To Prevent Blindness involve 1970 numbers projected to 1980.
12 These statistics should be used with caution, because the data are old and predate the more recent development of more successful treatment of cataract.

Table 1.--Prevalence of Cataract by Age Group
(cases per 1,000 people)

	52-64 yrs	65-74 yrs	75-85 yrs
Framingham Eye Study (1975):			
Lens opacity:			
Men	37.9	68.1	88.2
Women	44.7	76.7	93.0
Cataract:			
Men	4.3	16.0	40.9
Women	4.7	19.3	48.9
	45-69 yrs	**70-84 yrs**	
Nat. Health Interview Survey (1982):			
Cataract:			
Males	24.6	112.9	
Females	34.6	217.6	

SOURCES: **Framingham data:** U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, Vision Research: A National Plan--Report of the Cataract Panel, NIH Pub. No. 84-2473 (Bethesda, MD: 1987).
National Health Interview Survey data: M. LaPlante, "Data on Disability From the National Health Interview Survey, 1983-85," prepared for the National Institute on Disability and Rehabilitation Research, U.S. Department of Education, Washington, DC, in press.

The data in table 1 give an indication of the prevalence of cataracts before the large increase in cataract surgery that has occurred in the 1980s. As the numbers in that table show, cataracts occur with high frequency in older populations, and the phenomenon increases with age. Thus, as the number of elderly people increase, the absolute number of people with cataract is likely to increase.

The only effective treatment for cataract, cataract surgery, is described below. Cataract surgery can be performed at various points in the maturation of the cataract, depending, for example, on judgments about the extent to which the cataract interferes with the patient's life. A general shift to earlier surgery would increase the absolute number of procedures done (see discussion below).

CATARACT SURGERY: THE TECHNOLOGY

Cataract surgery--resorted to when a cataract becomes visually disabling--involves the removal of the clouded natural lens of the eye through an incision in the cornea or sclera (white part of the eye) (U.S. DHHS, PHS, 1987). As described below, the surgery may involve various methods, the most common of which are intracapsular extraction methods and extracapsular extraction methods (U.S. DHHS, PHS, 1987). Following extraction of the cataract, the surgical incision is closed by sutures (stitches), which may or may not need to be removed.

To regain vision after the natural lens has been removed, the patient must receive some type of prosthetic (artificial) replacement lens. The replacement may involve either an intraocular lens (IOL) implanted at the time of surgery or afterward, a contact lens, cataract eyeglasses, or some combination of these, depending on factors such as the patient's ability to wear a contact lens, the refractive status of the patient's other eye, and the age of the patient. In 1987, IOLs were placed in 85 percent of cataract procedures (Reuter and O'Sullivan, 1987). IOLs are not without certain problems, but they do offer several optical and other advantages over cataract glasses and contact lenses (U.S. DHHS, PHS, 1987). Furthermore, IOLs are generally preferred in the case of elderly patients, many of whom may have trouble manipulating and adapting to contact lenses (Jaffe, 1984).

Increasing Use of Posterior Chamber IOLs

IOLs have undergone continuous evolution in design, weight, and manufacturing processes since their introduction after World War II (U.S. DHHS, PHS, 1987). The first truly successful IOLs were anterior chamber IOLs, lenses placed in the anterior chamber of the eye, under the vault of the cornea, and in front of the iris (Safir, 1983). The pressure of an anterior chamber lens

against the tissues holding it sometimes causes disturbances that can be serious (Safir, 1993), and in recent years, posterior chamber IOLs have been rapidly gaining in popularity over anterior chamber IOLs. Posterior chamber IOLs are lenses placed in the posterior chamber, the place behind the iris from which the patient's own natural lens has been removed (Safir, 1983). From an optical point of view, the posterior chamber is the desirable place to put an IOL (although the undesirable long-term effects of posterior chamber lenses have probably not all become evident yet) (Safir, 1983).

In 1983, 48 percent IOLs placed were posterior chamber IOLs and 45 percent were anterior chamber IOLs (the remaining 7 percent were iridocapsular or iris fixation IOLs) (Stark et al., 1983). From February 1987 to February 1988, 91 percent of IOLs placed were posterior chamber IOLs and 9 percent were anterior chamber IOLs (Stark, 1988).

Advances in Surgical Techniques[13]

In recent decades, improvements in the techniques of cataract surgery and the implantation of IOLs have made cataract surgery one of the safest and most successful of all major operations (U.S. DHHS, PHS, 1987). Despite some of the advances, which are discussed further below, however, significant postoperative complications may occur in patients who undergo this surgery (U.S. DHHS, PHS, 1987).

Improved techniques in cataract surgery were made possible by improvements in preoperative medications, operative anesthesia, operating microscopes, and various microsurgical instruments

13For those who are interested, much of this discussion was drawn from "How Ophthalmology Has Changed During My Career," a fascinating paper on technological and other changes in ophthalmology prepared for OTA in 1983 by A. Safir.

(Safir, 1983). By the mid-1960s, the operation of choice for cataract removal was a technique known as intracapsular cataract extraction (Safir, 1983). The intracapsular technique involves removing both the natural crystalline lens of the eye and all of its surrounding capsule. Following an intracapsular cataract extraction procedure, the patient usually gets an anterior chamber IOL.

If a patient's lens is removed by the intracapsular extraction technique, an IOL placed in the posterior chamber will be resting against the vitreous body and may easily dislocate and slide down onto the retina, where it can do harm and be inaccessible to surgical removal (Safir, 1983). Consequently, surgeons choosing to put IOLs in the posterior chamber have revived interest in a technique known as extracapsular cataract extraction, which leaves the posterior portion of the lens capsule in place to support the IOL (Safir, 1983). Extracapsular extraction, by preserving the biologic separation of the vitreous body from the anterior chamber, decreases the risk of a vision-threatening complications such as as aphakic retinal detachment,[14] bullous keratopathy,[15] or cystoid macular edema.[16]

Until recently, intracapsular extraction was the preferred method of extraction, because the extracapsular extraction technique was difficult and left lens fragments in place that impaired the patient's vision. Since the development of posterior chamber IOLs (Reuter and O'Sullivan, 1987) and improved surgical techniques that permit an ophthalmologist to perform an

14Aphakic retinal detachment is the detachment of the retina which occurs in association with the loss or absence of a lens and may be physiologically related to removal of the lens.
15Bullous keratopathy is a noninflammatory disease of the cornea.
16Cystoid macular edema is a condition that involves swelling in the macula, which is the very highly specialized part of the retina that is responsible for fine, high-resolution, central vision acuity (Safir, 1983). The accumulation of fluid in the macula causes blurring of vision and may result in loss of central vision.

extracapsular extraction without leaving lens fragments behind, extracapsular extraction has gained in popularity. As of 1987, the vast majority (93.5 percent) of lens extractions were extracapsular extractions (Sanders, 1987).

Innovations in the techniques of cataract surgery are continuing. Microchip technology has permitted the development of a new technique for removing a natural lens called phacoemulsification. In phacoemulsification, the natural lens is ultrasonically fragmented and then is removed through a small (3 mm) incision (Nevyas, 1986). The use of phacoemulsification plus a new foldable silicone or hydrogel IOL will permit much smaller (3 mm as compared to 12 mm) incisions in patients who are candidates for this type of surgery. Smaller incisions in these patients may mean reduced postoperative astigmatism and fewer complications (Nevyas, 1986). Although only 13.2 percent of cataract extractions in 1987 involved phacoemulsification, the use of this technique is increasing (Sanders, 1987). Currently, the use of the newest types of IOLs--soft, foldable IOLs--is associated with slightly higher complication rates, including postoperative inflammation and occasional lens extrusion[17]; over time, however, outcomes with foldable lenses may be expected to improve (Sanders, 1987).

How Advances in Technology Have Altered Cataract Surgery

The development of more advanced technologies, including microsurgical techniques and instruments, has altered the nature of cataract surgery in several ways. First, the technical training required for doing cataract surgery has increased, and the equipment required for treatment is considerably more complex. Second, the precision and predictability of cataract surgery have improved considerably. Improved vision now occurs in the vast majority (94 to 96 percent) of cataract patients who undergo surgery (Allen and Hui-rong, 1987; Ruther and Black,

17Lens extrusion is displacement of the lens from the posterior chamber.

1987; Stark et al., 1983). Third, the medical risk of cataract surgery to the patient has decreased (Jaffe, 1984). Finally, because of improvements in techniques, cataract surgery today involves a much shorter hospitalization or is done on an outpatient basis (Jaffe, 1984). In 1966, the average length of stay for cataract surgery was 7.6 days; in 1977, it was 4.8 days; and in 1984, it was 2.1 days for those having inpatient surgery (Reuter and O'Sullivan, 1986). Currently, 96 percent of Medicare cataract surgery is done on an ambulatory basis (Ahern, 1988).

Increasing Number of Procedures

In recent years, the absolute number of cataract removal procedures has increased (Biomedical Business International, 1987; Sanders, 1987). Although there is some disagreement as to the exact number of cataract removal procedures are performed today, there is a consensus that cataract removal procedures are being done at an increasing rate. In 1983, approximately 700,000 cataract extractions were performed and 500,000 IOLs were implanted in the United States (Jaffe, 1984). Biomedical Business International reports 1.1 million IOLs were placed in 1987 and projects that the market for such lenses will grow at a rate of 7 percent per year to 1990; since IOLs are placed in the large majority of patients who undergo cataract surgery, the increasing market for IOLs reflects growth in the number of cataract removal procedures (Biomedical Business International, 1987). Sanders estimates that 1 million cataract removal procedures will be performed in 1988 (Sanders, 1987).

What accounts for the increasing performance of cataract surgery is not entirely clear. Some might argue that because of improvements in surgical techniques that have reduced the risks of cataract surgery and allowed the shift of cataract surgery from hospital to ambulatory settings,

the decision about whether to perform cataract surgery may be more likely to be made in favor of surgery now than it was in the past. The decision about whether to perform cataract surgery, like all medical decisions, should involve consideration of the risks and the benefits for a particular patient. The decision should be influenced by: 1) how severe a patient's cataract is, 2) how debilitating the cataract is for the patient when his or her particular life situation is considered, and 3) how the risks of cataract surgery weigh against the benefits for the particular individual. With technical improvements and decreased risks associated with the cataract extraction procedure plus improved visual rehabilitation of patients receiving IOLs, the balance of this equation may have tipped toward surgical extraction for more patients. Another view, however, is that the increasing number of surgical procedures may result in part from reduced thresholds for the performance of cataract surgery brought about by an overabundance of ophthalmologists (Greenberg, 1988; Trobe and Kilpatrick, 1983).

MEDICARE POLICIES: RECENT CHANGES THAT AFFECT CATARACT CARE

In 1980 and 1986, Congress amended the definition of "physician" in the Social Security Act to enlarge the scope of vision services that optometrists can receive reimbursement for under Medicare, while at the same time it recognized the preeminence of States in establishing and controlling optometrists' scope of practice.[18] In 1986 and 1987, the Health Care Financing Administration (HCFA) issued instructions to Medicare carriers[19] to clarify how Medicare would pay for surgical care when the postoperative or other services related to surgery are provided by someone other than the attending surgeon. These laws and instructions, discussed further below, have been interpreted by some Medicare carriers in such a way as to allow optometrists to bill for postoperative services to cataract surgery patients. Especially since 1986, optometrists have been increasingly billing Medicare for postoperative services related to cataract surgery (Marsalek, Aug. 24, 1988).

18Some services are specifically excluded from Medicare coverage, regardless of whether they are performed by doctors of medicine, osteopathy, or optometry and regardless of whether they are authorized by a State. Exclusions include: 1) routine eye examinations not performed to diagnose a specific symptom or complaint, and 2) eye examinations for the purpose of prescribing, fitting, or changing eyeglasses or contact lenses for refractive errors (as opposed to prosthetic lenses required by an individual lacking the organic lens of the eye).
19Part B of the Medicare program is administered on a day-to-day basis through contracts negotiated between the Federal Government and State-based health insurance carriers. It is the responsibility of the carriers to apply policies regarding benefits and limitations in accepting or rejecting bills submitted for reimbursement and to determine that charges made for covered services are reasonable (U.S. DHEW, 1976).

Recent Changes in the Social Security Act and Regulations

In 1980, Congress amended the Social Security Act to expand the range of vision services optometrists could provide and receive payment for under Medicare via Section 937 (Optometrists' Services) of the Omnibus Reconciliation Act of 1980 (OBRA-80, Public Law 96-499). Section 937 of OBRA-80 eliminated a provision of the Social Security Act limiting Medicare payment to optometrists to payment for "establishing the necessity for prosthetic services" and replaced it with a provision limiting Medicare payment to optometrists to payment for "services related to the condition of aphakia" (Sec. 937 (a)).[20] Aphakia was defined in the Code of Federal Regulations as "the absence of the natural crystalline lens of the eye, regardless of whether an intraocular lens has been implanted" 42 CFR 410.23 (10-1-87 ed.). Section 937 provision became effective July 1, 1981 (Sec. 937 (c)).

Federal regulations implementing Section 937 specified that if the services were related to aphakia and authorized by the State in which the optometrist practiced, an optometrist could receive Medicare reimbursement for "examination services" including case history, external examination, ophthalmoscopy,[21] biomicroscopy,[22] tonometry,[23] evaluation of fields of vision, evaluation of ocular motility, evaluation of binocular function, and examinations required to prescribe prosthetic lenses in connection with aphakia (42 CFR 410.23 (10-1-87 ed.)). During the period 1980 through 1986, relatively few optometrists billed Medicare directly for the

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20OBRA-80 put into effect HEW's 1976 recommendation (U.S. DHEW, 1976) that Medicare Part B reimbursement be extended to optometrists for services related to aphakia (see app. A). OBRA-80 also called upon the U.S. Department of Health and Human Services to submit to Congress by January 1, 1982, legislative recommendations with respect to Medicare reimbursement for "services furnished by optometrists in connection with cataracts and such other services as they are legally authorized to perform."

21Ophthalmoscopy is the inspection of the internal structure of the eye using illumination and magnification.

22Biomicroscopy is the inspection of frontal tissues of the eye using illumination and magnification.

23Tonometry is the measurement of the internal pressure of the eye.

postoperative care of cataract surgery patients, but it was common in some areas for an ophthalmologist who used an optometrist's services for postoperative care of a patient to bill Medicare for the full global fee for the surgery and then pay the optometrist directly for the followup services (Mitchell, 1988).[24]

In 1986, Congress amended the Social Security Act via Section 9336 (Vision Care) of the Omnibus Reconciliation Act of 1986 (OBRA-86, Public Law 99-509). Section 9336 of OBRA-86 expanded the services that an optometrist could be reimbursed for by Medicare to include all services covered by Medicare "which he is legally authorized to perform as a doctor of optometry by the State in which he performs them. . . ." (Sec. 9336 (a)). This provision became effective April 1, 1987 (Sec. 9336 (b)). Since that time, HCFA has issued several instructions giving guidance to Medicare carriers on dealing with Medicare claims procedures and reasonable charges under the provision.

Recent Changes in Instructions to Medicare Carriers

Since 1986, HCFA has issued several sets of instructions to Medicare carriers that have been interpreted as sanctioning Medicare reimbursement to optometrists for postoperative services related to cataract surgery. Medicare carriers generally pay a "global fee" for cataract and other surgery. The global fee typically covers the presurgical evaluation of the patient, the surgery,

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24In a case in North Carolina, an ophthalmologist billed the Medicare carrier (Prudential) a global fee for cataract surgery and then paid the optometrist who provided postoperative care out of pocket (Marsalek, Aug. 24, 1988). The Inspector General's Office did not approve of this, and on January 13, 1986, the carrier issued instructions that called for separate billing and procedure codes by the operating ophthalmologist and the optometrist who provided routine post-cataract-surgery care (the surgeon was to use the modifier "-54" with the appropriate surgical procedure code to show that the bill was for the surgery only, and the optometrist was to use the new procedure code W9245) (Prudential Insurance Co., 1986). Subsequently, some optometrists began billing Medicare directly for some postoperative services related to cataract surgery (Marsalek, Aug. 24, 1988).

itself, and the postoperative followup visits (Mitchell, 1988). HCFA's carrier instructions, summarized below, established billing procedures that some carriers have used to allow the splitting of a global fee for cataract surgery between an ophthalmologist who performs cataract surgery and an optometrist who provides followup care. An ophthalmologist billing these carriers places the modifier "-54" at the end of the surgical procedure code to indicate that his or her bill is only for the surgery and does not include postoperative care; the optometrist who provides postoperative care adds the related modifier "-55" to indicate that his or her bill is for postoperative services only (Mitchell, 1988). The Medicare carrier reduces the global payment to the ophthalmologist by an established percentage (ranging from 5 to 30 percent at different carriers) of the normal global fee for surgery, and the difference (or some other amount) goes to the optometrist who performs the followup visits (Mitchell, 1988).

In March 1986, HCFA issued an instruction to Medicare carriers to clarify how Medicare would pay for surgical care when the surgery and related services are provided by more than one physician. That instruction, summarized below, was a general instruction that did not specifically pertain to cataract surgery.

- Revision 1146, March 1986: "Sec. 5248: Making Reasonable Charge Determinations When Physicians Fragment Previously Global Charges": Many surgeons, including ophthalmologists, typically render preoperative care, the operative care, and the postoperative care related to a surgery and bill Medicare one fee, termed a global fee, for all care. In cases where the care is provided by more than one physician,[25] and if a global fee was in effect in 1973, reimbursement to individual physicians cannot exceed the global prevailing fee adjusted by the economic index (U.S. DHHS, HCFA, March 1986).

25Effective July 1, 1981, as a consequence of OBRA-80, an optometrist is considered a "physician" (i.e., eligible for reimbursement) by Medicare when rendering services related to aphakia; and effective April 1, 1987, as a consequence of OBRA-86, an optometrist is considered a "physician" by Medicare when rendering services that optometrists are legally authorized to render by the State in which the optometrist practices.

Following the enactment of OBRA-86, HCFA issued several additional sets of carrier instructions to help implement the new law and to make its March 1986 instruction specific to services pertaining to cataract surgery. Those instructions are summarized below.

1. Revision 1182, April 1987: "Sec. 2020.25: Optometrists"
   A. Services Furnished Through March 31, 1987
   B. Services Furnished After March 31, 1987. As mandated by OBRA-86, Sec. 9336, effective April 1, 1987, a doctor of optometry is considered a physician with respect to all services the optometrist is authorized to perform under State law or regulation.
   C. General Claims Guidelines. Ophthalmologists performing cataract surgery have historically charged a single global fee that encompasses the presurgical evaluation of the patient, the surgery itself, and the postoperative followup care. Since some of the postoperative services are also covered when furnished by optometrists, the carrier should establish a screening mechanism to identify inappropriate or duplicative services. If an ophthalmologist charges a global fee for cataract surgery but another physician (e.g., an optometrist) furnishes some of the postoperative services, the portion of the global fee that represents services not furnished by the ophthalmologist should be disallowed; and the optometrist who provided the postoperative care should be reimbursed for the allowed services that he or she performs (U.S. DHHS, HCFA April 1987a).

2. Revision 1182, April 1987: "Sec. 5250: Reimbursement for Cataract Glasses, Contact Lenses and Related Services, and Optometrists' Services":
   A. Cataract Glasses, Contact Lenses, and Related Services
   When postoperative services encompassed by a carrier's global allowance for cataract surgery are performed by someone other than the surgeon, the physician submitting the bill for surgical care only should add the modifier "-54" to the code used for the surgical procedure. The physician who provides covered postoperative services only should add the modifier "-55" to the code for the surgical procedure. In addition, all physicians should be asked to submit to the carrier a narrative description of the care they provided so that the carrier can make appropriate payment determinations (U.S. DHHS, HCFA, April 1987b).

3. Revision 1208, August 1987: "Sec. 5250: Reimbursement for Cataract Glasses, Contact Lenses and Related Services, and Optometrists' Services":
   B. Other Medical and Health Services Furnished by Optometrists
   Beginning with services furnished on or after April 1, 1987, Medicare will pay for all other covered medical and other health services furnished by a doctor of optometry which are reasonable and medically necessary and which he or she is legally authorized to perform by the State in which he or she practices.
   C. Use of Charge Data To Determine Reasonable Charges for Optometrists' Services
      1. Customary Charges.
      2. Prevailing Charges.

> 3. Global Allowances. When an optometrist performs covered services that a Medicare carrier ordinarily pays for as part of a global allowance for a surgeon's (e.g., ophthalmologist's) service, the payment amounts should be determined in accordance with the applicable guidelines including Sec. 2020.25.C, which emphasizes the need to avoid making duplicative payments. Consequently, when a carrier pays for an optometrist's covered services in accordance with Sec. 5250B and the services are normally reimbursed through a global allowance for surgery, the total of the separate allowances for the services of the surgeon and the optometrist may not exceed the applicable global prevailing fee for the surgery (U.S. DHHS, HCFA, August 1987).

The interpretation of HCFA's instructions in the case of perioperative care for cataract surgery patients has varied among carriers, who traditionally are allowed great discretion in interpreting instructions from HCFA's central office. At least one Medicare carrier has interpreted the instructions in such a way as to allow individual ophthalmologists to assign some percentage of their global fee for surgery to an optometrist who provides postoperative care (Aetna Life Insurance Co., 1988). In a letter dated May 20, 1988, HCFA's Office of Reimbursement Policy said it prefers that ophthalmologists and optometrists bill separately for their services and that Medicare carriers--rather than providers with possible incentives to give kickbacks for referrals--determine payment amounts (U.S. DHHS, HCFA, May 20, 1988).

Evolving Arrangements for the Delivery of Perioperative Care

Although there have been anecdotal reports of cataract surgery being practiced with extensive optometric involvement in postoperative care (American Optometric Association, August 1988; Hoffman, 1987, 1988a, 1988b; Root, Feb. 15, 1988), systematic evaluations of the nature or extent of optometrists' role in providing preoperative or postoperative care for cataract surgery patients are not available.

The Inspector General's Office of the U.S. Department of Health and Human Services, analyzing preliminary data from a study of postoperative cataract care (involving the

examination of payments made on behalf of 1,000 Medicare beneficiaries plus interviews with 58 ophthalmologists and 28 optometrists), found that 97 percent of the payments reviewed involved a global fee for cataract surgery and only 3 percent involved a split fee; however, 28 percent of the ophthalmologists interviewed permit optometrists to provide postoperative care (Mitchell, 1988). Scientifically reviewed evaluations of the role optometrists play in providing postoperative cataract care are currently being worked on by HCFA and the U.S. General Accounting Office (Ahern, 1988: Baugher, May 10, 1988).

Surveys of patterns of practice may help illuminate the nature and extent of cooperative or other arrangements between optometrists and ophthalmologists for the provision of postoperative cataract care. Other useful information might be derived from evaluations of how practice patterns are related to factors such as geographic region or rural vs. urban area and evaluations of the economic costs and incentives for various parties involved.

THE TRADITIONAL MODEL OF CARE FOR PATIENTS UNDERGOING CATARACT SURGERY

Traditionally, the ophthalmologist who performs a patient's cataract surgery is responsible for the patient's care from the preoperative evaluation through the completion of the patient's healing process. An initial diagnostic screen and a postoperative visit for refraction following cataract surgery may be provided by an optometrist. But the ophthalmologist who performs a patient's surgery provides a preoperative evaluation to assess the patient's fitness for cataract surgery and all of the postoperative visits following cataract surgery (except, in some cases, the visit for refraction). A typical course of visits for a cataract surgery patient under the traditional model of care is shown in table 2.

Preoperative Assessment of Cataract Surgery Patients

As noted in table 2, the initial diagnostic evaluation of a patient with a cataract may be done by an optometrist, who then makes a judgment about whether to refer the patient to an ophthalmologist for further evaluation and possible cataract surgery. In deciding whether to refer a patient, the optometrist should perform a thorough eye examination and consider such things as the amount of visual interference the patient experiences, how much the interference is likely to worsen, whether the cataract affects one or both eyes, and the health of each eye; the optometrist should also consider the patient's medical history (Nevyas, 1986). In deciding which ophthalmologist to send a patient to, the optometrist should consider such things as the ophthalmologist's track record and access to equipment needed to ensure a good outcome (Nevyas, 1986).

Table 2.--Typical Course of Visits for a Cataract Surgery Patient Under the Traditional Model of Care

	Purpose/concerns	Procedures used
Initial diagnostic screen*	To detect cataract	Diagnostic procedures to detect cataract, evaluate eye health
Preoperative surgical evaluation	To assess need and fitness for for cataract surgery	Diagnostic procedures to diagnose cataract, evaluate eye health; gather information about systemic health
Surgery	To remove cataract	Surgery
Postoperative visits	To optimize surgical outcome	Diagnostic and therapeutic procedures (e.g., prescribe or administer drugs, perform surgery)
Day 1	Inflammation Infection Secondary glaucoma Bleeding Wound leaks	
Day 3-5	Infection Secondary glaucoma Bleeding Wound leaks	
Week 2-3	Delayed infection Retinal disease Suture-induced astigmatism	
Week 6	Suture-induced astigmatism	
Week 6-12*	Final refraction	Prescription for corrective lenses

*NOTE: Traditionally, the visits for the initial diagnostic screen and for refraction following cataract surgery may be provided by either an optometrist or an ophthalmologist. All the other visits are provided by the ophthalmologist who performs a patient's surgery.

SOURCES: American Optometric Association, Alexandria, VA, personal communication, August 1988; N.S. Jaffe, Cataract Surgery and Its Complications, 4th ed. (St. Louis, MO: C.V. Mosby Co., 1984); H.R. Stokes, Secretariat for Governmental Relations, American Academy of Ophthalmology, Florence, SC, personal communication, Aug. 9, 1988; and I.G. Wong, Kaiser Permanente Medical Care Program, Northern California Region, Redwood, CA, personal communication, Apr. 2, 1988.

A referring optometrist or primary care physician may very well use some of the same examinations and diagnostic tests in a diagnostic assessment as an ophthalmologist or other surgeon uses in a preoperative evaluation of a patient. Traditionally, however, the evaluations by the optometrist and the ophthalmologist are separate. The reason is that an ophthalmologist contemplating cataract surgery for a patient needs to gather information to make a variety of preoperative judgments.

In order to make sound preoperative judgments regarding the advisability of cataract surgery for a particular patient, the appropriate surgical procedure, the advisability of implanting an IOL, and the setting in which surgery should be performed, the ophthalmologist should perform a preoperative evaluation to assess:

- o the effect of the cataract on the patient's vision and lifestyle,
- o the overall health of the patient's eye, and
- o the patient's general health.

The severity of visual loss from a cataract can be measured in various ways, but the general consensus is that it is not just the loss of visual acuity that should be measured in determining the need for cataract surgery but the cataract's effect on the patient's life functioning (Jaffe, 1984). The overall health of the patient's eye should be assessed by the ophthalmologist for several reasons. One reason is to evaluate the patient's suitability for surgery. In the case of a patient with optic nerve damage behind the cataract or amblyopia,[26] for example, correction of the patient's cataract will not correct the patient's vision problems (Nevyas, 1986). Some ocular conditions (e.g., previous retinal detachment) may be contraindications for implanting an IOL (Jaffe, 1984). Other ocular problems (e.g., ocular structural deformity, corneal disease, extreme

26Amblyopia is a condition of poor visual acuity resulting from various congenital and/or developmental abnormalities of the eye.

myopia, and glaucoma) may alert the ophthalmologist to the possibility of certain complications and affect judgments regarding the appropriate type of surgery to perform and how to manage the patient postoperatively (Coonan et al., 1985; Jaffe, 1984; Sherif and Dardenne, 1981).

The patient's general health should be evaluated by an ophthalmologist to identify serious systemic medical conditions (e.g., heart disease, hypertension, or diabetes) that affect the risks and benefits of surgery for the patient (Jaffe, 1984). In a population of elderly individuals, who are from the age group in which most cataracts occur, the likelihood that concurrent systemic disease is present is fairly high. According to one standard text, systemic conditions seldom preclude the possibility of cataract surgery:

> Cataract surgery has progressed to the point where only rarely need a patient be refused surgery because of physical disability. However, the surgeon must exercise good judgment when considering surgery on feeble aged and infirm individuals. Cataract surgery is usually unjustified on a patient with an overwhelming medical problem such as a terminal stage of malignancy. If an intelligent medical workup is obtained, most temporary contraindications can be eliminated (Jaffe, 1984, p. 5).

If cataract surgery is performed, the information about a patient's general health that is gathered during a preoperative assessment may affect the preoperative, surgical, or postoperative management of the patient. If a patient is severely anemic, has an active peptic ulcer, has uncontrolled colitis, or has uncontrolled diabetes, for example, the problem will have to be corrected prior to surgery (Jaffe, 1984). If a patient is taking anticoagulant medications, the medications will have to be stopped prior to surgery (Jaffe, 1984; Nevyas, 1986). If a patient is a frail elderly person with cardiovascular disease and uncontrolled diabetes or hypertension, a decision may be made to perform cataract surgery in the hospital rather than in a physician's office or other outpatient setting. It is especially important to know whether systemic steroids or antibiotics may be used safely in case of postoperative complications (Jaffe, 1984). In some

cases, there may be a need to involve the patient's internist in the patient's preoperative and postoperative care.[27]

Postoperative Care of Cataract Surgery Patients

The purpose of the postoperative care of a cataract surgery patient is to monitor healing and to take whatever steps are necessary to help ensure the best possible surgical outcome. The typical course of postoperative care for cataract surgery patients involves 5 to 10 visits, depending on the problems that arise postoperatively (Jaffe, 1984; Wong, 1988).

Postoperative visits are scheduled to occur at times that will overlap with the peak periods of risk for the complications that are of greatest concern (see table 2). At the first postoperative visit, the attending ophthalmologist performs an evaluation to assess postoperative inflammation and to detect problems such as infection, secondary glaucoma, bleeding, or wound leaks. An eye check is performed on the third to fifth day after surgery, timed to occur when the risk of infection is highest (Stokes, 1988). Between the second and sixth weeks after surgery, checks for suture-induced astigmatism and retinal disease are performed. During each of these postoperative visits, the attending ophthalmologist reassesses medication dosages, adjusts the patient's sutures as deemed necessary, and performs other assessments and patient management tasks. Some time between the sixth and twelfth weeks after cataract surgery, the patient visits either an ophthalmologist or an optometrist to be measured for refractive errors of the eye and be given a prescription for glasses to correct the errors (American Optometric Association,

27Ophthalmologists do not themselves always perform presurgical physical examinations. In uncomplicated cases, for example, an intake physical may be performed by the anesthesiologist who has to deal with systemic emergencies during surgery. For patients who have pre-existing conditions that mitigate against the advisability of outpatient surgery, a presurgical physical is almost always handled as a "consult" from "medicine" (internal medicine) (Greenberg, 1988).

August 1988). As soon as healing from cataract surgery is complete, the patient may return to his or her primary eye care provider (an ophthalmologist or optometrist) for routine eye care.

What is significant about each postoperative exam following cataract surgery is not simply what is examined but what judgments and adjustments in patient management are made at the time of the exam. Cataract surgery patients may develop any of a number of postoperative complications (as discussed in a separate section below) that must be managed appropriately if the surgery is to be as successful as possible. In the case of postoperative inflammation, for example, judgments have to be made about whether the inflammation is normal or is a sign of a serious problem. Although some inflammation after cataract surgery is inevitable, the degree of inflammation and its significance varies--depending on such things as the patient, the type of surgery, the difficulty of the lens extraction, and the skill of the ophthalmic surgeon, and on whether the patient develops an infection or other postoperative complication. In some patients, inflammation can be treated by adjusting steroid dosage,[28] but in other patients, excessive inflammation may be a sign of endophthalmitis, a vision-threatening intraocular infection (Jaffe, 1984; Piest et al., 1987). Endophthalmitis may require treatment with antibiotics injected into the eye or surgery; if appropriate treatment is not initiated within hours, the patient may lose the eye (Jaffe, 1984; Wong, 1988; Zach, 1988).

Other judgments and adjustments are also required. Some patients may require adjustments in their medications. Patients with glaucoma, for example, may need special management of intraocular pressure (Sherif and Dardenne, 1984). Reducing suture-induced astigmatism may require the surgeon to adjust or cut the sutures, and it is important that the adjustments be made at the proper time--cutting the sutures too early could overcorrect the astigmatism and

28Many States do not allow optometrists to prescribe steroids (Stokes, 1988).

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make the wound leak, whereas cutting them too late could make the suture-induced astigmatism permanent (Nevyas, 1986).

Should a postoperative systemic problem related to pre-existing systemic disease (e.g., diabetes or hypertension) arise in a cataract surgery patient, the ophthalmologist's most likely and prudent course of action would be to send the patient to an internist (Greenberg, 1988).

EVALUATING ALTERATIONS IN THE TRADITIONAL MODEL OF CARE

The traditional model of care for cataract surgery patients--in which the attending ophthalmologist performs a preoperative evaluation and nearly all of the postoperative care--is rooted in surgical traditions that transcend the field of ophthalmology. According to the principles of the American College of Surgeons:

> The responsibility of a surgeon includes preoperative diagnosis and care, the selection and performance of the operation, and postoperative surgical care. . . . It is unethical to turn over postoperative care completely to the referring physician (Am. College of Surgeons, 1985).

The College of Surgeons further states:

> An ethical surgeon will not perform surgery at a distance from his usual location without personal determination of the diagnosis and the adequacy of preoperative preparation. He will personally render the postoperative care unless it is delegated to another physician as well qualified to continue the essential aspects of total surgical care (Am. College of Surgeons, 1985).

Given the long history, as well as the medical and ethical foundations of the traditional model of care for cataract surgery patients,[29] it seems reasonable to suggest that deviations from that model--some of which may already exist (American Optometric Association, August 1988; Greenberg, 1988, Mitchell, 1988, Myers, 1988)--should be closely scrutinized for effects on the quality of care.

OTA found no scientific studies of patient outcomes when optometrists provide preoperative or postoperative care for cataract surgery patients. Consequently, direct comparisons between the quality of perioperative care provided to cataract surgery patients by optometrists and ophthalmologists could not be made.

29The legal aspects of this model of care are beyond the scope of this Staff Paper.

In the absence of scientific studies of outcomes associated with alterations in the traditional model of care for cataract surgery patients, conclusions about the medical wisdom of an expanded role for optometrists in the provision of preoperative or postoperative care for cataract surgery patients must be based on considerations of:

1. the nature of possible postoperative complications following cataract surgery and the skills that may be needed to help prevent or manage those complications;
2. differences in the training of optometrists and ophthalmologists that might affect the quality of care that these professionals are able to provide to cataract surgery patients in the perioperative period; and
3. general models of arrangements for the provision of postoperative care by a health professional other than the attending surgeon.

In considering the appropriateness of moving away from traditional arrangements for the provision of perioperative care to cataract surgery patients, a point that should be made is that the process of diagnosis differs significantly from the process of patient management. Diagnosis is the act of identifying a disease or condition from its signs and symptom. Patient management is the process a caregiver engages in when treating a patient for a diagnosed condition. In an initial diagnostic evaluation, the focus is on arriving at the correct diagnosis of a patient's condition; in managing a patient, the focus is evaluating the patient and undertaking whatever medical or other procedures are needed to help ensure a good outcome. Patient management is more complex than diagnosis in that it involves making repeated observations and judgments about a patient's condition and fitting them into an overall process of care. The preoperative evaluation of a surgical patient and the provision of postoperative care intended to ensure a good surgical outcome are both patient management tasks. Even though some of the procedures involved in diagnosis and the management of a surgical patient are similar, the skill and

judgment required may be significantly different.[30]

Potential Postoperative Complications of Cataract Surgery

In terms of improving vision, cataract surgery is generally cited as being 94- to 96-percent successful (Allen and Hui-rong, 1987; Ruther and Black, 1987). Food and Drug Administration figures indicate that 84.6 percent of 50,537 study eyes with IOLs had 20/40 vision or better (Stark et al., 1983). It is important to note that these figures are based on care provided by ophthalmologists and give no indication of how many surgical or postoperative ocular complications or other problems were dealt with before the final outcome was achieved. The numbers also do not indicate how the success rate varies among elderly or other populations that are medically vulnerable because of concurrent ocular or systemic disease.

Cataract surgery involves numerous types of postoperative complications. Examples of a few such complications are shown in table 3. These include endophthalmitis, severe postoperative inflammation, corneal edema, bullous keratopathy, pupillary block, secondary glaucoma, intraocular hemorrhage, wound leakage or rupture, cystoid macular edema, detached retina, pupillary displacement, iris prolapse, subluxation or dislocation of the lens, touching of the cornea by the IOL, and opacities of the posterior capsule (Jaffe, 1984; Nevyas, 1986; Safir, 1983).

30In diagnosis, physical examinations and diagnostic testing are used to develop and then narrow the list of possible causes of disease. In managing patients' disorders, the same procedures are used to assess the effectiveness of treatment and to measure the success of alternative manipulations.

Table 3.--Examples of Postoperative Complications Associated With Cataract Surgery

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Endophthalmitis--Endophthalmitis is a severe, sometimes painless, intraocular infection that can be caused by any of several bacterial or fungal micro-organisms. It may cause a violent inflammatory reaction in the eye and can produce loss of vision. A patient with endophthalmitis should be seen by an ophthalmologist within hours, so that appropriate treatment with systemic antibiotics (sometimes injected into the eye), surgery, or other means can initiated before there is permanent loss of vision (Deutsch and Goldberg, 1984, Jaffe, 1984; Mauriello, et al., 1983).

Severe inflammation--A certain degree of inflammation after cataract surgery is normal. In some cases, severe intraocular inflammation that resembles endophthalmitis develops. Treatment of severe postoperative inflammation often involves the use of steroids (Jaffe, 1984).

Corneal edema and bullous keratopathy--Corneal edema, swelling in the layers that make up the cornea of the eye, is one of the most serious complications of cataract surgery. The more traumatic the surgery, the more edema will occur; edema may also occur when there is sharply raised pressure. If edema lasts longer than a few days, there may be serious corneal damage, and the patient should get medical or surgical treatment. In the worst cases, corneal edema may develop into bullous keratopathy and require a corneal transplant (Jaffe, 1984; Nevyas, 1986).

Pupillary block--Pupillary block occurs when the vitreous moves against the iris or interferes with communication between the anterior and posterior chambers. It happens most often when patients receive an anterior chamber IOL. If the surgeon doesn't take medical or surgical treatment to remedy pupillary block promptly, it can lead to chronic angle closure glaucoma (Jaffe, 1984).

Secondary glaucoma--Glaucoma is damage to the optic nerve caused by pressure in the eye greater than the eye can stand. The types of secondary glaucoma that may may arise following cataract surgery are numerous (e.g., malignant, sodium hyaluronate, hemolytic glaucoma; glaucoma associated with pseudoexfoliation, peripheral anterior synechias, pupillary block, epithelialization of the anterior chamber, fibrous ingrowth, phacoanaphylaxis, iris atrophy, postoperative inflammation, free vitreous in the anterior chamber, or hyphema). Treatment may require the prompt administration of topical or oral drugs to lower intraocular pressure or even surgery (Jaffe, 1984; Jensen, 1988).

Intraocular hemorrhage--Hemorrhage (bleeding) in the eye may take one of three forms: hyphema (bleeding into the anterior chamber), vitreous hemorrhage, or expulsive hemorrhage. Any of these may be extremely dangerous. The sudden occurrence of an expulsive hemorrhage, though extremely rare, is one of the most dangerous complications of cataract surgery. Surgical treatment must be initiated at once to prevent loss of the eye (Jaffe, 1984).

Wound rupture--A cataract wound may rupture or tear, often as a result of postoperative trauma. Most wound ruptures need to be promptly repaired by the surgeon (Lambrou and Kozarsky, 1987).

Cystoid macular edema--Cystoid macular edema involves swelling of the macula, the highly specialized part of the retina that is responsible for fine, high-resolution, central vision acuity. The problem is often associated with vitreous loss during surgery. The accumulation of fluid in the macula causes blurring of vision and may result in loss of central vision. If the problem does not resolve on its own, it may require treatment with an oral, nonsteriod anti-inflammatory drug such as indomethacin, local or systemic steroids, or even surgery (Nevyas, 1986; Jaffe, 1984; Safir, 1983).

Detached retina--The risk of retinal detachment is greater following intracapsular cataract extraction than following extracapsular extraction and is greater when a patient loses some vitreous during cataract surgery. If small peripheral holes are detected early, the surgeon may be able to do cryosurgery to prevent the holes from causing retinal detachment. If the retina does become detached, however, major intraocular surgery will be required to repair it (Coonan et al., 1985; Nevyas, 1986).

Pupillary displacement--The pupil may become distorted after surgery as a consequence of trauma or vitreous loss during surgery. Over time, the adhesion of vitreous strands to the retina can cause a detached retina. The surgeon may cut vitreous strands with a YAG laser (Nevyas, 1986).

Iris prolapse--Iris prolapse is the protrusion of a part of the iris through a wound in the cornea. Iris prolapse makes the eye vulnerable to infection. If the protrusion is large, the surgeon will have to excise or replace it (Jaffe, 1984; Nevyas, 1986).

Displacement of the IOL--An IOL sometimes become displaced from its normal position. If it stays in the area of the pupil, it is considered subluxated; if it is moves completely away from the pupil, it is considered luxated, or dislocated. The approaches for managing a patient with a displaced lens vary, depending in part on the position of the lens. In some cases, treatment may involve surgical removal of the displaced lens and the implantation of a new lens (Allara and Weinstein, 1987; Jaffe, 1984).

Touching of the cornea by the IOL--An IOL that makes physical contact with the cornea, even on an intermittent basis, is a serious problem, because the plastic used in most IOLs (PMMA) can kill the cornea's endothelial cells, eventually leading to opacification of the cornea and the need for a corneal transplant. An IOL that is touching the cornea must be removed by the surgeon.

Opacities of the posterior capsule--Approximately 40 percent of patients who have extracapsular cataract extraction surgery--the surgery now used in more than 90 percent of cases--will develop sufficient opacification of the posterior capsule as to necessitate a second procedure (e.g., YAG laser capsulotomy or surgical capsulotomy) to let light rays pass through undistorted (Safir, 1983).

SOURCES: N.S. Jaffe, Cataract Surgery and Its Complications (St. Louis, MO: C.V. Mosby Co., 1984; H.J. Nevyas, "How To Manage the Cataract Patient," Review of Optometry, pp. 46-56, July 1986; and A. Safir, "How Ophthalmology Has Changed During My Career," prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1983.

Other postoperative complications associated with cataract surgery that are not shown in table 3 include delayed restoration, late loss, or late shallowing of the anterior chamber of the eye; Descemet's membrane detachment; choroidal detachment; postoperative optic neuritis; macular changes from postoperative hypotension; macular pucker and preretinal membrane; vitreoretinal traction syndrome; postoperative rupture of the anterior hyaloid membrane; hemosiderosis oculi; hemophthalmitis; uveitis; vitreous incarceration in the wound; sympathetic ophthalmitis; retained lens material; phacoanaphylactic uveitis; phacotoxic uveitis; epithelial cysts and downgrowth; fibrous ingrowth; IOL uveitis; IOL glaucoma; IOL hyphema; pupillary capture, and postoperative patient trauma (Hibbs, 1987; Jaffe, 1984).

Some of the available evidence on the rates of certain complications of cataract surgery is cited below. Since postoperative care has traditionally been provided by ophthalmologists, available evidence is based on cataract surgery patients for whom ophthalmologists provided the postoperative care.

Estimating overall complication rates among cataract surgery patients is difficult for several reasons. Rather than considering overall complication rates, most of the available medical literature considers rates of specific complications (e.g., Bartov et al., 1984; Coonan et al., 1985). Other studies do examine overall complication rates but only for particular surgical procedures or types of IOLs (e.g., Arnott and Condon, 1985; Kielar and Stambaugh, 1982; Shearing, 1983; Smith et al., 1987). For some complications (e.g., cystoid macular edema), the complication rates increase over time, so the longer the period of a study, the higher the rate of complication would be[31] (Jaffe, 1984; Lakhanpal and Schocket, 1987). Another problem is that the technology of cataract surgery is advancing so fast that if a study follows a large series of

31One could measure the complication rate per month of followup to address this problem, but OTA found no studies that used this approach.

patients over a long period of time, the results of the study may be obsolete before the study is even complete.

Shearing did a study of postoperative complications among a group of 100 cataract surgery patients in whom a posterior chamber IOL was implanted between March 1977 and February 1978; these patients had no concurrent ocular disease at the time of their surgery and would generally be expected to do well (Shearing, 1983). Of the 100 patients in this study, 56 were followed for more than 4 years, and 35 were followed more than 5 years; 9 patients were lost to followup between 6 and 12 months. Of the patients who were followed, 6 developed retinal detachments, 4 developed secondary glaucoma, and 1 developed severe cystoid macular edema. Two of the patients developed problems related to the presence of the IOL. At the end of their followup, 90 percent of the patients followed in this study had visual acuity of 20/40 or better. Four patients had vision of less than 20/200, including three who were blind (one from retinal detachment, two from central vascular occlusions).

Allen and Hui-rong analyzed complications in 416 eyes (in 358 patients) that underwent extracapsular cataract extraction surgery for simple senile cataracts from July 1977 through June 1983 (Allen and Hui-rong, 1987). The 416 eyes were divided into two groups: Group I for eyes that had no ocular disorders other than senile cataract at the time of cataract surgery (315 eyes, or 76 percent of the 416); and Group II for eyes that did have concurrent ocular disorders (e.g., diabetic retinopathy, repaired retinal detachment, glaucoma, macular degeneration, uveitis) at the time of cataract surgery (101 eyes, or 24 percent of the 416 eyes).[32] Some of the patients in

32The fact that 24 percent of eyes in this study had other eye disease at the time of cataract surgery suggests that success rates of cataract surgery measured only for healthy eyes offer just one part of the picture. No measures of the general health of the population receiving cataract surgery were found in any studies reviewed by OTA.

each group had a posterior chamber IOL implanted in addition to extracapsular cataract extraction surgery (150 of the 315 eyes in Group I, and 36 of the 101 eyes in Group II). The incidence of certain postoperative complications for the two groups of eyes in Allen and Hui-rong's study, all of which were followed up for at least 3 months, is shown in table 4.

Table 4.--Incidence of Selected Postoperative Complications of Cataract Surgery (measured as incidents per 100 eyes operated)

Complication	Allen and Hui-rong[a]	Stark et al.[b]
Endophthalmitis	.63 and 0	Not listed
Corneal edema	.63 and 1.0	.09 to 5.5
Retinal detachment	2.53 and .99	.76 to 3.5
Secondary glaucoma	.63 and 0	0 to 2.9
Cystoid macular edema	4.1 and 5.9	Not listed
Hyphema	1.26 and 0	Not listed
Subluxation of IOL	.95 and 0	.29 to 6.0
Opacification of the posterior capsule	19.0 and 17.8	0 to 20

[a]The figures from Allen and Hui-rong's study reflect incidents among eyes without concurrent eye disease at the time of cataract surgery (Group I) on the left and incidents among eyes with concurrent eye disease at the time of surgery (Group II) on the right. The figures for each group combine figures for patients who had extracapsular cataract extraction surgery alone and for patients who also received a posterior chamber IOL (see text for discussion).

[b]The numbers from Stark et al.'s study reflect the range of rates among eyes that underwent various methods of combined cataract extraction and IOL implantation (see text for discussion).

SOURCES: A.W. Allen and Z. Hui-rong, "Extracapsular Cataract Extraction: Prognosis and Complications With and Without Posterior Chamber Lens Implantation," Annals of Ophthalmology 19:329-333, September 1987; W. Stark, A.E. Maumenee, M. Datiles, et al., "Intraocular Lenses: Complications and Visual Results," Tr. Am. Ophth. Soc. 81:281-309, 1983.

Allen and Hui-rong measured a broader range of complications than that shown in table 4 and found an overall postoperative complication rate of 30.2 incidents per 100 eyes operated.[33] Among patients without concurrent eye disease at the time of cataract surgery, Allen and Hui-rong found an overall postoperative complication rate of 31.4 incidents per 100 eyes operated. Among patients with concurrent eye disease at the time of cataract surgery, Allen and Hui-rong found an overall postoperative complication rate of 26.7 incidents incidents per 100 eyes operated. All of the postoperative complications that Allen and Hui-rong measured would require judgment concerning the most appropriate intervention. Clearly, however, some of the complications (e.g., opacification of the posterior capsule) are far less serious than others (e.g., endophthalmitis).

Table 4 also shows the incidence of postoperative complications among cataract surgery patients found in a study by Stark et al. (Stark et al., 1983). This study examined 1,344 eyes that underwent combined cataract extraction and IOL implantation: one group of 1,041 eyes that underwent extracapsular cataract extraction surgery and got a posterior chamber IOL, one group of 103 eyes that underwent intracapsular cataract extraction surgery and got an iris-clip lens sterilized by the dry-pack method, and one group of 200 eyes that underwent intracapsular cataract extraction surgery and got an iris-clip lens sterilized by the wet-pack method. For patients who got a posterior chamber IOL, the mean followup time was 12 months, with a range of 3 to 44 months. The age and ocular disease status of patients in the Stark et al. study differed from those of patients in Allen and Hui-rong's study. Furthermore, although the technology used in both studies was 1980s technology, the surgical technique and lens type in the two studies were not identical. Nevertheless, the incidence rates for certain complications

33The data do not indicate how many individuals were involved. It is likely that some individuals had multiple complications. Thus, 30.2 incidents may have occurred in only 15 or 20 eyes.

found in the two studies did fall in similar ranges.

The data on postoperative complications in table 4 suggest that the successes of cataract surgery in terms of improving vision are achieved not just because of the good preoperative management and the technical quality of the surgical procedure but also because of the successful postoperative management of the ocular complications that develop. Some of the ocular complications of cataract surgery occur in the general population, but others (e.g., endophthalmitis, expulsive hemorrhage, iris prolapse, wound rupture, dislocated IOL) occur primarily in patients who have undergone cataract or other eye surgery (Jensen, 1988). A person who has been trained to perform eye surgery and has had clinical experience in the postoperative management of cataract surgery patients might be better able to recognize such complications than an individual without such training. A number of postoperative complications in cataract surgery patients are associated with certain types of surgical procedures or IOLs (e.g., the risk of a detached retina is greater following intracapsular extraction than following extracapsular extraction; pupillary block occurs more often when patients receive an anterior chamber IOL than when they receive a posterior chamber IOL) or with certain types of problems during surgery (e.g., endophthalmitis, cystoid macular edema, corneal edema, secondary glaucoma, retinal detachment, vitreous hemorrhage, and pupillary displacement may be associated with loss of vitreous during surgery) (Coonan, 1985; Jaffe, 1984). The surgeon who operates on a patient might be more alert to the possibility of these types of complications than a person who was not familiar with the specific procedure a patient underwent.

Finally, it should be noted that some postoperative complications associated with cataract surgery require intervention that only an ophthalmologist or other physician can provide. The treatment of a detached retina, for example, involves eye surgery that only an ophthalmologist

can perform. The treatment of bacterial endophthalmitis and other conditions may require the use of antibiotics, steroids, or other drugs with systemic effects that must be prescribed by a licensed physician.

Education and Clinical Training of Ophthalmologists and Optometrists

In the absence of scientific evaluations of data comparing the outcomes of care for cataract surgery patients treated in the perioperative period by ophthalmologists and optometrists, a question that arises is whether differences in the education and training of the two types of professionals might affect their ability to provide good quality perioperative care.[34]

There are no standardized tests or board exams taken by both ophthalmologists and optometrists, so the most plausible method of comparing the knowledge base of the two professions is to assess their educational and training programs. To compare the education and clinical training of ophthalmologists and optometrists, OTA reviewed literature pertaining to professional standards, literature from the professional organizations of both ophthalmologists and optometrists, and literature from several institutions that provide education and clinical training in either ophthalmology or optometry. In addition, OTA staff made direct observations at two institutions--at the ophthalmology residency program at Wills Eye Hospital in Philadelphia and at the Pennsylvania College of Optometry in Philadelphia.

Ophthalmology Education and Training

Ophthalmology is a surgical specialty of medicine and is regulated by State laws that govern medical practice. Ophthalmologists are licensed as medical doctors by State boards of medical

34A recent OTA report on indicators of the quality of medical care found that physicians practicing in the area of their training were more likely to provide good quality care than

examiners. There is no specific licensure of ophthalmologists (Stokes, 1988). Individuals who have 1) successfully completed specified medical, postgraduate clinical, and ophthalmologic residency training (see below), 2) received a valid and unrestricted license to practice medicine in the United States; and 3) passed written and oral examinations can be certified as diplomates by the American Board of Ophthalmology (American Board of Ophthalmology, 1987). That board is recognized by the American Board of Medical Specialties, which assists its members in the evaluation and certification of physician specialists (Council on Graduate Medical Education, 1988). The vast majority (90 percent) of ophthalmologists are board certified (Root, Sept. 29, 1988).

In order to be certified by the American Board of Ophthalmology, an ophthalmologist must undergo an 8-year education and training program after college that includes training in systemic disease and experience with patients in a variety of settings, as well as specific classroom, clinical, and surgical training for the treatment of eye disease (American Board of Ophthalmology, 1987). The 8-year program involves three stages:

- o 4 years of medical school,
- o 1 year of postgraduate clinical training in a hospital-based program,
- o 3 years of training in a hospital-based ophthalmology residency program.

Medical schools in the United States, Canada,[35] and Puerto Rico are accredited by the Liaison Committee on Medical Education, a joint committee of the American Association of Medical Colleges and the American Medical Association (Carlson, 1988). Voluntary accreditation standards for graduate medical education and for residency training in the United States are set

physicians practicing in other areas (U.S. Congress, OTA, 1988).
[35]Medical schools in Canada are coaccredited by the Liaison Committee and the Committee on the Accreditation of Canadian Medical Schools (Carlson, 1988).

by the Accreditation Council for Graduate Medical Education. That organization is sponsored jointly by the American Board of Medical Specialties, the American Hospital Association, the American Medical Association, and the Council of Medical Specialty Societies (Council on Graduate Medical Education, 1988).

Prior to admission to medical school, a student is usually expected to complete a 4-year undergraduate degree, including specific courses in chemistry and other sciences, and must meet high scholastic and medical school entrance examination standards (Stokes, 1988). About 15 percent of medical schools allow students to enter after the third year of college (Association of American Medical Colleges, 1987).

Conventionally, the first 2 years at an accredited medical school emphasize coursework (lectures and laboratories) in sciences basic to medicine. In the first 2 years of medical school, a medical student typically gets between 1,500 and 2,000 hours of coursework. About 1,250 hours of this is coursework in basic medical sciences such as anatomy, pathology, physiology, microbiology, biochemistry, pharmacology, neuroscience, behavioral science, preventive medicine, and genetics (Assoc. of Amer. Medical Colleges, 1987). The rest is coursework in various topics related to medical practice.

The last 2 years of medical school emphasize clinical rotations in hospitals and other settings. During clinical rotations, a medical student gets an opportunity, under the direct supervision of faculty and resident physicians, to develop skills in examining and evaluating patients; during clinical rotations, a medical student has "limited opportunities to assume personal responsibility for patient care and generally do[es] not participate in the care of individual patients for an

extended period of time" (American Medical Association, 1987). On average, a medical student spends about 80 weeks or, assuming a 40-hour week[36], 3,200 hours doing clinical rotations (Assoc. of Amer. Medical Colleges, 1987). On average, at least 50 of the weeks, or 2,000 hours, are spent doing rotations in basic medical specialties such as internal medicine, surgery, pediatrics, family/community medicine, and psychiatry); the remaining 30 or so weeks (1,200 hours) are spent doing rotations in various electives (Assoc. of Amer. Medical Colleges, 1987).

In preparation for becoming a licensed physician, a medical school graduate does a 1-year internship at a hospital in a field such as internal medicine, pediatrics, surgery, family practice, or emergency medicine. Traditionally, an intern is the first person "on call" to examine and admit patients to the hospital and is "on call" every third or fourth night to cover various activities in the hospital. In many cases, therefore, an intern works as many as 80 to 100 regular and on-call hours a week (Glickman, 1988; McCall, 1988). An intern who works an 80-hour week (e.g., 45 regular hours and 35 on-call hours) for 50 weeks would get a total of 4,000 hours caring for patients with a variety of medical problems. The certification requirements of the American Board of Ophthalmology specify that at least 6 months of an ophthalmologist's 1-year internship must be "broad experience in direct patient care" (American Board of Ophthalmology, 1987). An intern who works 40 regular hours a week for 26 weeks (6 months) gets 1,040 hours of clinical experience in the evaluation and treatment of patients with a variety of medical conditions. This figure--1,040 hours of experience in direct patient care--does not include any on-call hours and is therefore an absolute minimum.

To receive specialized hospital-based training in ophthalmology, a physician must enter a 3-year ophthalmology residency program. In order to be accredited, an ophthalmology residency

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36A 40-hour week does not include "on call" hours.

program must include 360 hours of didactic instruction in basic and clinical sciences relevant to ophthalmology; 288 hours of clinical conferences attended by faculty and other resident physicians; and lectures, conferences, and a minimum of 50 hours in ocular pathology (American Medical Association, 1987). At some ophthalmology residency programs, these minimums are significantly exceeded. At the residency program at Wills Eye Hospital in Philadelphia, for example, students get 822 hours of didactic instruction in basic and clinical sciences, 504 hours of clinical conferences, and 210 hours of ocular pathology (Jeffers, 1988).

The core of an ophthalmology residency program, more important in some respects than didactic instruction, is clinical experience in managing patients with eye problems and in performing eye surgery. An accredited residency program offers a resident:

1) at least 3,000 outpatient visits distributed through a broad range of ophthalmic disease, with "major management responsibility under [faculty] supervision" in at least 2,000 visits,
2) surgical experience in performing and assisting at ophthalmic surgery of various types, including a minimum of 25 cataract procedures and 10 strabismus procedures,
3) consultation experience involving a minimum of 150 patients and covering a wide spectrum of ophthalmic diseases and ophthalmic manifestations of systemic diseases (American Medical Association, 1987).

Some ophthalmology residency programs offer clinical experience that far exceeds these accreditation minimums. At the residency program at Wills Eye Hospital in Philadelphia, for example, a resident manages, under supervision, about 15,000 patients with eye disease (Jeffers, 1988). A resident at Wills is involved in over 600 cases of eye surgery; in 350 to 400 of these (including 90 to 95 cataract surgeries), the resident is the primary surgeon and provides

the patients' followup care; in the other cases, the resident assists during surgery (Jeffers, 1988).

Optometric Education and Training

In its 1976 report on optometrists (see app. A), HEW noted that the Institute of Medicine of the National Academy of Sciences had defined an optometrist as follows:

> The Doctor of Optometry (O.D.) is a health professional who performs eye examinations to determine the presence of visual, muscular, or neurological abnormalities, and prescribes lenses, other optical aids, or therapy such as eye exercises to enable maximum vision. Optometrists are trained to recognize disease conditions of the eye and ocular manifestations of other diseases, and to refer patients with these conditions to the appropriate health professional (U.S. DHEW, 1976, p. 21).

In 1976, neither this nor any other single definition of optometry was used in all State laws (U.S. DHEW, 1976). State laws at the time varied with respect to licensure requirements for optometrists, allowed scope of optometric practice, and continuing education requirements for optometrists (U.S. DHEW, 1976).

In 1988, the definitions of optometry and the licensure requirements for optometrists still vary from State to State. As a condition of optometry licensure, however, all States do require optometric training, as well as passage of the exam offered by the National Board of Examiners in Optometry and/or the exam offered by the State optometric board (Mays, July 8, 1988). Since 1976, many States have expanded the scope of optometric practice. As of June 1988, all States but Maryland[37] permitted optometrists to use certain drugs, under various controls, to diagnose eye problems; and 23 States permitted optometrists to use certain drugs, under various controls, to treat eye problems (Mays, July 8, 1988). In no State are optometrists licensed to perform surgery or to provide the full range of medical procedures that might be required to manage all of the ocular postoperative complications of cataract surgery.

37A bill to permit the use of such drugs in Maryland was vetoed by the Governor in June 1988.

Optometrists undergo a professional training program that is customarily 4 years in length.[38] There are 16 professional optometric degree programs in the United States (including Puerto Rico) and 2 additional programs in Canada (Mays, July 8, 1988). All 18 of the programs are accredited by the American Optometric Association's Council on Optometric Education (Council on Optometric Education, August 1988), which is a member of the Council on Postsecondary Accreditation (Mays, July 8, 1988). Furthermore, all schools and colleges of optometry are regionally accredited by the same agency that accredits other colleges and universities in the region (Boerner, 1988).

An individual seeking admission to a professional optometric degree program must have a minimum of 2 years of college, although most of the applicants (77.7 percent) have a baccalaureate or higher degree (American Optometric Association, August 1988). Applicants are also required to take the optometry college admission test.

To receive accreditation from the Council on Optometric Education, an optometric degree program does not have to conform to externally imposed requirements for the curriculum or clinical training it offers its students:

> In its evaluation of an optometric educational program, the Council will consider the stated objectives, what it seeks to accomplish for the student, the profession, and the public, and how well it succeeds in realizing these objectives. . . . . The Council encourages curriculum experimentation, the development of institutional individuality, and the achievement of excellence without the establishment of uniformity (Council on Optometric Education, 1983/1984, pp. 24-25).

During their 4-year training program, optometry students in different programs get varying amounts of didactic instruction (lectures and laboratories) in basic medical sciences, in ocular science, and in optics and lens design and application (Illinois College of Optometry, 1988;

38Some professional optometric degree programs are 4-year programs, with training running 32 to 36 weeks per year; others are 3-year programs, with training running 44 to 48 weeks per year (Council on Optometric Education, 1983).

Pennsylvania College of Optometry, 1988; Southern College of Optometry, 1987). At the Pennsylvania College of Optometry, students get about 1,800 hours of didactic instruction, including about 700 hours of didactic instruction in basic medical sciences (e.g., gross anatomy, biochemistry, microanatomy, physiology, pharmacology, endocrinology), about 700 hours of didactic instruction in ocular science (e.g., glaucoma/ocular emergencies, neuro eye disease), and about 400 hours of didactic instruction in optics (e.g., advanced contact lenses) (Pennsylvania College of Optometry, 1988). At other institutions, the hours and courses offered are different (Illinois College of Optometry, 1988; Southern College of Optometry, 1987). At the Southern College of Optometry, for example, students receive more than 900 hours of didactic instruction in basic sciences (Southern College of Optometry, 1987).

In the latter 2 years of their training, optometry students typically get supervised placements in various college-based clinical settings and in off-campus clinical settings ranging from private optometric practices to institutional settings such as optometry clinics, nursing homes, health maintenance organizations, and hospitals (Boerner, 1988: Illinois College of Optometry, 1988; Mays, July 8, 1988; Mullen, 1986; Pennsylvania College of Optometry, 1988). Through these clinical placements, optometry students get an opportunity to provide eye examinations and fit patients for corrective lenses, with supervision from other optometrists. Optometry students also get some exposure to a smaller number of patients with eye disease, in some cases working under the supervision of physicians who hold faculty appointments with the college (Illinois College of Optometry, 1988; Pennsylvania College of Optometry, 1988; Southern College of Optometry, 1987). By the time they graduate, students at the Pennsylvania College of Optometry have seen a total of about 1,200 patients, some of whom have eye disease

(Pennsylvania College of Optometry, 1988). Furthermore, they have followed some of the preoperative care and some of the postoperative care for about 8 to 60 patients undergoing eye surgery (Lewis, 1988). The clinical experience of students at other schools of optometry may very well differ.

Following graduation from an optometry program, some optometry students participate in a 1-year hospital-based or other optometric residency program (Mays, Sept. 22, 1988). Optometric residency programs are accredited by the American Optometric Association's Council on Optometric Education (Council on Optometric Education, 1985). Each of the accredited optometry residency programs is affiliated with a school or college of optometry, and many of the accredited programs are located at Veterans Administration facilities (Council on Optometric Education, 1987).

Comparison of Ophthalmologic and Optometric Training

OTA found that the training of ophthalmologists and optometrists differs quantitatively, and perhaps qualitatively, in at least three areas of potential significance to their ability to care for cataract surgery patients before and after surgery:

1) clinical training in the evaluation and treatment of patients with a variety of medical problems,
2) clinical training in the management of patients with eye disease, and
3) clinical training in the management of patients undergoing eye surgery.

As a physician, an ophthalmologist gets 3 years of clinical training (2 years of clinical rotations as a medical student and 1 year as an intern) in the evaluation and treatment of patients with medical problems. At no point in an optometrist's training is comparable clinical training in the

evaluation and treatment of systemic disease offered. It can be reasonably hypothesized that clinical training in the evaluation and treatment of patients with systemic medical problems would affect the quality of a caregiver's judgments with respect to the management of a cataract surgery patient before and after cataract surgery. Systemic diseases such as diabetes mellitus, chronic obstructive pulmonary disease, and hypertension are common in candidates for cataract surgery, and such diseases can affect the risks and benefits of surgery, the likelihood of postoperative complications, and decisions about the postoperative management of ocular or systemic complications requiring the administration of antibiotics or other drugs with systemic effects. Even though an ophthalmologist may not actually treat a patient's systemic conditions, an ophthalmologist's training as a physician may enhance his or her ability to evaluate a patient's general health and make judgments about the need to refer the patient to an internist for the treatment of complications related to systemic conditions.

As an ophthalmology resident, an ophthalmologist gets 3 years of clinical training in the evaluation and treatment of patients with serious eye problems. An ophthalmology resident is responsible for making judgments about patients with ocular and related problems and for signing orders. By observing, treating, and taking responsibility for the care of patients with ocular and other problems, an ophthalmology resident gets a chance "to develop diagnostic, therapeutic, and manual skills and judgment as to their appropriate use" (American Medical Association, 1987). An optometrist gets substantial clinical training in the performance of eye evaluations but gets significantly less experience in the evaluation and treatment of patients with serious eye problems. It can be reasonably hypothesized that a person who has observed and managed a large number of patients with serious eye problems would be more likely to have developed skills in managing rare problems (or, in fact all such problems) than a person who has

seen a smaller number of patients and has generally not managed their care.

Finally, the difference between ophthalmologists and optometrists in terms of their exposure to surgery and, more importantly, to patients who have recently had eye surgery is worthy of note. An ophthalmology resident performs cataract and other eye surgery and manages patients' postoperative care. An optometry student gets considerably less exposure to patients who have undergone eye surgery and does not have responsibility for managing patients' postoperative care.

General Models for the Provision of Postoperative Care by Caregivers Other than the Attending Surgeon

In the absence of scientific evaluations of the outcomes of perioperative care provided to cataract surgery patients by optometrists, it may be instructive to review models outside the field of ophthalmology in which caregivers other than the attending surgeon are involved in providing postoperative care. It is important to note, however, that none of models described below are exactly comparable to a situation in which an optometrist practicing at a site where the attending ophthalmologist is not readily available assumes responsibility for most of the cataract surgery patient's postoperative visits. Differences include such things as the complexity of the surgery that is performed, seriousness of possible postoperative complications, clinical training and experience of the supplemental caregivers, the practice setting and types and extent of supervision by the attending surgeon, and the State laws and regulations governing the scope of practice of the supplemental caregivers.

In some instances, part of a patient's postoperative care is provided by a physician other than the attending surgeon. In teaching hospitals, for example, a resident who was part of an operating team may provide followup care to a surgical patient for at least part of the postoperative period; typically, the care provided by the resident is reviewed and supervised by the attending surgeon. In the case of patient who undergoes cardiac surgery, the patient's cardiologist may take over some of the patient's postoperative care from the cardiac surgeon and be reimbursed by Medicare under the "-54"-modifier arrangements described earlier (Marsalek, June 15, 1988). In both these examples, the individuals providing postoperative care are physicians who, like the attending surgeon, have been trained in the evaluation and treatment of systemic disease and have had specific training in the area of medicine related to the patient's surgery. Also, in the first example, the resident providing postoperative care would know the details of the patient's surgery.

In some instances, health professionals who do not hold medical degrees but are trained to provide medical care and/or nursing care may provide some postoperative care after a physician has performed surgery.[39] Physician assistants, who have 2 years of academic and clinical training in a medical school setting (LeRoy, 1981), are specifically trained and registered in almost all States to provide certain services under the supervision of a physician (U.S. Congress, OTA, 1986). Physician assistants are considered by State laws to be agents of physicians (Cawley, 1988), and some States limit the number of physician assistants that a physician can supervise to one or two (Miller & Byrne, Inc., 1978). Physician assistants do provide some postoperative care (e.g., wound inspection), but the care is generally provided in a hospital under the supervision of the attending surgeon or another physician and is limited to services

39Dentists and podiatrists are trained and licensed to perform some limited types of surgical procedures, in some cases under medical supervision; as the attending surgeons, they also provide the postoperative care.

for which the physician assistant has been specifically trained. In some States, under some conditions, physician assistants can provide care if the physician is not on the premises (e.g., if an orthopedic surgeon is operating), but the physician assistant must be able to communicate with the physician immediately (Cawley, 1988). Nurse practitioners, who receive training beyond that required for an RN license in a particular specialty such as midwifery or family practice, may also provide some routine postoperative care in inpatient settings and in health maintenance organizations. In these settings, the surgeon or some other physician (e.g., a resident) would be available to deal with any problems that arose (Edmonds, 1988). Visiting nurses provide postoperative nursing care, but they have been specifically trained to do this, and in most States, the law requires that a physician authorize the plan for care and sign a certificate saying that he or she has seen the patient (Edmonds, 1988).

At least four potential areas of concern arise in circumstances where an attending surgeon shares postoperative care with a nonphysician caregiver at a geographically separate site. One concern is that when someone other than the attending surgeon provides a patient's postoperative care, continuity of care may be diminished. Having the attending surgeon or another person who is familiar with the exact nature of the surgery the patient underwent provide or supervise postoperative care enhances continuity. Surgical technique varies from surgeon to surgeon, and the response to surgery varies from patient to patient, so the quality of the postoperative observation may be related to the knowledge an observer has of the nature of the specific surgeon's technique in using a procedure and of the variables that would change a particular patient's postoperative response. Many would argue--and this argument is the basis of the traditional model of care--that the best and most consistent observer would be the operating surgeon. The surgeon would be aware of the usual response patients had to his or her own surgery. The surgeon would also be aware of any subtle variations in his or her technique that arose in a particular patient's case and that might alter the expected postoperative response.

A second concern is that when a caregiver other than the attending surgeon who does not have medical or surgical training is involved in providing care to a surgical patient, consistency of care may be diminished. Consistency of care results when the examinations and diagnostic procedures given to a patient by different caregivers are uniform. It can occur only if all the caregivers who are evaluating a patient after surgery have had appropriate training, including an adequate amount of supervised clinical exposure to the types of patients who are to be assessed and to the possible complications that may arise. The caregivers must also be up-to-date in their training. In situations where nonphysician caregivers such as nurse practitioners or physician assistants are involved in providing postoperative care, consistency of care is enhanced by frequent onsite review by a physician, who has a close relationship with nonphysician caregivers.

A third concern is that when someone other than the attending surgeon is involved in the postoperative management of a surgical patient and the caregivers are at separate sites, there may be delays in care. If an emergency or other serious problem arises and the patient is not promptly transferred to a caregiver who has the medical or other skills needed to treat the problem, there may be irreversible damage to the patient's health. In order to prevent delays in care, cooperating caregivers must arrange for 24-hour patient coverage, and the patient must know who is responsible for care and be given easy and prompt access to the appropriate caregiver.

A fourth concern is that when a caregiver who does not have medical training is involved in the postoperative management of a surgical patient, the management of patients' systemic health problems may be inadequate. Physicians get education and clinical training that gives them exposure to patients with a range of systemic medical conditions that can affect surgical

outcomes or be affected by certain types of drugs. A caregiver who has not had clinical training in the evaluation and treatment of systemic medical problems may not be able to manage patients' systemic problems following surgery appropriately.

The extent to which the four concerns just raised are addressed in existing comanagement arrangements for cataract surgery patients between optometrists and ophthalmologists has not been evaluated. As noted earlier, no scientific evidence to indicate what happens when postoperative care for cataract surgery patients is provided by someone other than the attending surgeon has yet been collected.

FINDINGS AND CONCLUSIONS

Congress requested that OTA assess the medical safety and appropriateness of optometric involvement in preoperative and postoperative care provided to cataract surgery patients. A report prepared by HEW in 1976 (U.S. DHEW, 1976) addressed several issues pertaining to optometric involvement in caring for Medicare patients, but did not present definitive conclusions on the role optometrists should play in preoperative and postoperative management of cataract surgery patients. Since 1976, there have been changes in the technology of cataract surgery and changes in Medicare laws, regulations, and carrier instructions that have led some optometrists and ophthalmologists to challenge the traditional model of perioperative care for cataract surgery patients. Thus, an evaluation of the safety and appropriateness of deviating from the traditional model by expanding optometric involvement in such care is now appropriate.

Assessing the appropriateness of preoperative and postoperative care for cataract surgery patients by optometrists is difficult because of the absence of scientific data about the outcomes of care for cataract surgery patients provided by optometrists and ophthalmologists. In the absence of scientific evidence, conclusions about the medical wisdom of moving away from traditional patterns of care must be based on considerations of the possible postoperative complications following cataract surgery, differences in the education and training of ophthalmologists and optometrists that may affect their ability to provide perioperative care, and general medical models for the provision of perioperative care by caregivers other than an attending surgeon.

With regard to preoperative care, it is the current assessment of OTA that a preoperative evaluation prior to cataract surgery must be done by the ophthalmologist who is to perform the

surgery. Such an evaluation must include an evaluation of the risks and benefits of surgery to the patient and a decision as to the type of surgery. The preoperative evaluation must consider the patient's systemic health as well as the health of the patient's eye. Surgery is more than mere mechanics on an assembly line. Human individuality and biologic variability require a cognitive contribution to patient management, and this should be based on familiarity with the patient as well as medical science.

Allowing optometrists to engage in postoperative assessments of cataract surgery patients for all postoperative visits after the first one and to provide the visits at a site geographically separate from the attending ophthalmologist would be a significant departure from the traditional model of postoperative care for such patients. Potential risks of departing from the traditional model of postoperative care for cataract surgery patients include the following:

1. If an optometrist or other caregiver who is unfamiliar with the specific aspects of a particular patient's surgery is responsible for postoperative care, continuity of care and resulting quality of care may be adversely affected.
2. Optometric training may not give optometrists sufficient clinical exposure to the postoperative management of cataract surgery patients to allow them to make physical exams consistent with those of an attending ophthalmologist or to fit his or her exams into a regimen of postoperative patient management.
3. Optometric training does not give optometrists the medical or surgical skills needed to manage certain postoperative complications of cataract surgery. For patients who develop a problem that requires the involvement of the attending ophthalmologist (e.g., to prescribe systemic drugs that have to be prescribed by a physician or to perform eye surgery), delays as great as great as 12 to 24 hours might occur before the referral and consult by the attending surgeon could be completed, since few optometrists have 24-hour, weekend, on-call or emergency

coverage for their patients. For most patients with most complications, a delay would be an inconvenience. In a few cases (e.g., the occurrence of endophthalmitis), a delay of several hours could result in the loss of an eye or have other serious consequences for the patient's health.

The extent to which these concerns have been addressed in existing comanagement arrangements for the postoperative care of cataract surgery patients has not been evaluated. In spite of the absence of a known risk, cautious medical practice suggests we should be aware of the potential risks of giving optometrists an expanded role in providing postoperative care for cataract surgery patients. Moving away from the traditional model of care without a scientific assessment of the likely effects on patient outcomes runs the risk of reducing the quality of care patients receive. A more prudent approach would be to allow cautious alterations in the traditional model--alterations that address plausible hypothesized concerns--and then to evaluate the effects.

APPENDIX A--SUMMARY OF HEW'S 1976 STUDY OF OPTOMETRISTS

In July 1976, the U.S. Department of Health, Education, and Welfare (HEW) issued a congressionally mandated study entitled "Report to Congress: Reimbursement Under Part B of Medicare for Certain Services Provided by Optometrists" (U.S. DHEW, 1976). That study, performed by the Health Resources Administration (HRA) with the aid of nine expert consultants and assistance from a variety of Federal agencies, specifically examined the question, "What services related to aphakic and cataract conditions currently covered under Part B of title XVIII of the Social Security Act, when provided by a physician, are appropriate for reimbursement when provided by an optometrist?" The only services for which optometrists could receive Medicare reimbursement at the time the study was undertaken were services related to establishing the necessity for prosthetic lenses.

Conclusions and Recommendations by the U.S. Department of Health, Education, and Welfare

The conclusions of the 1976 HRA study were derived from "factual information, analytic findings, and professional judgments assembled during the study" (U.S. DHEW, 1976). The major conclusions are quoted below.

1. Qualifications of optometrists. Optometry is a profession qualified to provide a broad range of services beyond refraction and the provision of eyeglasses. Furthermore, the services provided appear to be effective in patient management, including the management of aphakic and cataract patients. They are reasonable, nonexperimental, safe, and generally acceptable to the vision/eye care community and the public.
2. Services related to aphakic and cataract conditions. Many of these services are the same as the specific diagnostic, therapeutic, and consultative services currently covered under Part B of Medicare when provided to pre- and post-surgery cataract patients by ophthalmologists or other doctors of medicine and osteopathy.
3. Detection and diagnosis of disease. Evidence presented during this study supports the conclusion that optometrists, in general, are qualified to provide services for the detection and preliminary diagnosis of ocular disease and ocular manifestation of systemic disease. Referral, where indicated, is made

to ophthalmologists and other health care practitioners for definitive diagnosis and medical or surgical treatment.

4. Standards of procedure. Clinical standards committees of professional associations have identified effective instrumentation and procedures that are available to and utilized by optometrists which are effective in the diagnosis/detection of disease, notwithstanding limitation by certain State jurisdictions regarding the use of topical drugs.
5. Quality assurance. Quality assurance is attainable in the provision by optometrists of reasonable, safe, nonexperimental, and acceptable services to all patients, including the Medicare-eligible population. The development of criteria of care for diagnostic, therapeutic, and consultative services provided by optometrists, and similar to those existing for other professional groups, does appear feasible in both organized and independent health care settings. Such criteria currently exist in a number of individual situations or are in various stages of development.
6. Access to services. Vision/eye care services for aphakic and cataract patients, as well as for patients more generally, can be made more accessible to the Medicare-eligible population by providing reimbursement for services when provided by optometrists. In general, optometrists are more widely distributed geographically and practice in many smaller communities where other vision/eye care practitioners are not available.
7. Equity. Financial equity can be extended to those Medicare beneficiaries who currently obtain necessary and reasonable health services from optometrists but who do not currently receive the reimbursement to which they should be entitled.
8. Delivery patterns. It is reasonable to infer that inclusion of services under Medicare for aphakic patients when provided by optometrists would not significantly alter existing provider deliver patterns within the vision/eye care community. However, the impact upon such delivery patterns of the inclusion of services by optometrists for cataract patients, while likely to be small, is less clear.
9. Costs. It is reasonable to infer that the inclusion of services related to aphakic and cataract conditions when provided by optometrists would result in some added costs to the Medicare program. These added costs would be partly associated with Medicare enrollees currently served by optometrists without reimbursement, as well as those patients not now receiving care, who would do so as a result of the inclusion of such services under Medicare. Estimates suggest, however, that such added costs would note be significant in the context of overall Medicare costs for vision/eye care services and service benefits. This is viewed particularly so in the instance of extended reimbursement for services provided by optometrists to aphakic patients.

On the basis of the 1976 report, the U.S. Department of Health, Education, and Welfare recommended that those services covered under Medicare for aphakic patients and within the scope of practice of optometrists be reimbursable under Part B when provided by optometrists. The Department said it would be inappropriate to extend Part B reimbursement coverage to include services to cataract patients prior to surgery when provided by optometrists.

> Overall vision/eye care financed through Medicare should not be adversely affected by adjustments to the present system. The Department believes that the problems and numbers of aphakic patients are definable, significant, and yet manageable enough to warrant such an adjustment. With respect to services provided by optometrists to cataract patients . . . the Department believes that the resolution of a number of issues should precede further consideration of any extension of reimbursement. These issues include development of an operational definition of cataract, patient health care implications, delivery pattern changes, cost implications, appropriate patient cost sharing, and administrative design and control against abuse. . . . The attached [HRA] study did not address such concerns in detail (U.S. DHEW, 1976).

Recommendations by Expert Consultants to the HRA Study

Separate recommendations and concerns were advanced by the nine expert consultants (three optometrists, three ophthalmologists, one optometric educator, and two public representatives) who aided in the preparation of the HRA study. In reviewing the study materials, the consultants concluded that steps should be taken immediately to extend reimbursement under Part B for services provided by optometrists to both aphakic and cataract patients (U.S. DHEW, 1976). Citing as a rationale "considerations of patient needs, qualifications of optometry to provide services effective in patient management, and increased access of Medicare beneficiaries to vision/eye care services," the consultants to the study recommended that covered services related to aphakia and covered services related to cataract conditions, when provided by optometrists, be reimbursable under Part B. For the reasons cited above, the Department of Health, Education, and Welfare did not endorse the consultants' second recommendation.

The expert consultants to the HRA study also raised several other points. One of these, for example, was the inconsistent application of coverage and reimbursement policies by individual carriers. Another was the possibility for improving patient care by enhancing working relationships between optometrists and ophthalmologists. These relationships could be strengthened, it was suggested, by means such as developing joint educational programs at the

undergraduate and graduate levels, establishing interdisciplinary clinics with optometrists and ophthalmologists working together, facilitating referral of patients between the optometrists and ophthalmologists when in the best relationship of the patient, and by joint development of quality standards for service and materials for by peer review mechanisms.

Limitations of the 1976 Study

At the time the 1976 study was undertaken, Part B coverage for cataract patients included, when provided by any doctor of medicine or osteopathy, 1) eye examinations, except that part of the examination related to refraction, if the examination was carried out in relation to a specific patient complaint; 2) surgical and related professional services carried out in connection with the removal of the lens; and 3) services in connection with the provision of both temporary and permanent prosthetic lenses, including fitting and providing the lenses themselves (U.S. DHEW, 1976). The only services for which optometrists might be reimbursed were dispensing services in connection with the actual fitting and provision of prosthetic lenses (U.S. DHEW, 1976). Neither the Department's recommendations nor the study on which those recommendations were based fully addressed the question of the appropriateness of having optometrists provide care for cataract surgery patients following their cataract surgery.

The recommendations and conclusions in the 1976 report were based on evaluations of the optometric and ophthalmologic practices that were in place at the time. The surgical techniques and the patterns of care for cataract surgery today are different from those of 1976. In 1976, cataract surgery was an inpatient procedure. The average hospital stay was 4.8 days in 1977 (Reuter and O'Sullivan, 1987). In the average case, an ophthalmologist performing the surgery would have been required to make in-hospital assessments for the first 5 days. As discussed in this OTA Staff Paper, technological changes since the 1976 report was issued have resulted in a shift of cataract surgery from inpatient settings to an outpatient settings. These changes mean

that postoperative cataract care that would have been given by the attending surgeon as inpatient followup during days 1 to 5 after cataract surgery can now be given on an outpatient basis.

Licensing restrictions on optometric care have also changed since 1976. In 1976, only eight States allowed optometrists to use pharmaceutical agents for purposes of diagnosing ocular disease, and no States allowed optometrists to prescribe therapeutic drugs. Currently, 49 States and the District of Columbia permit optometrists to use some drugs, under certain conditions, to diagnose eye disease, and 23 States permit optometrists to use some drugs, under certain conditions, to treat eye problems (Mays, July 8, 1988).

APPENDIX B.--ACKNOWLEDGMENTS

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GOVERNMENT GUIDELINES TO RATION CATARACT CARE COULD ACTUALLY INCREASE THE DEMAND FOR EYE SURGERY

UPLAND, CA.- Newly released government guidelines which attempt to ration cataract care could actually increase the demand for cataract care by as much as 35%, says Bill Sardi, a consultant to the eye care industry.

"These new guidelines were developed to covertly ration cataract care and prompt older Americans to delay a cataract operation, but may actually cause more senior Americans to become aware of the symptoms and problems caused by cataracts," says Mr. Sardi. The Agency for Health Care Policy Research (AHCPR) has began issuing self-assessment tests to prospective surgical patients. Once older Americans learn that cataracts are the cause of their vision problems they may be more likely to ask to have their cataracts removed, says Mr. Sardi."

Sardi says a 1992 report indicates only 16% of senior Americans actually know what cataracts are. Many are unaware they have cataracts and falsely believe problems such as falls and accidents, disinterest in activities and loss of independence are just a part of growing old. Actually cataracts progress so slowly they masquerade as signs of false senility, says Mr. Sardi.

Falsely assuming that many cataract operations are performed unnecessarily, the Agency for Health Care Policy Research now offers a list of common symptoms and problems caused by cataracts for prospective cataract patients to review. The checklist asks senior Americans to evaluate the visual difficulties they have with reading, watching TV, driving, as well as their degree of blurred vision, glare and double vision. More than 8,000 physicians and patients have already requested the government checklist.

"A 1990 Harris Poll estimated there were 15 million cases of undetected cataracts in the U.S.," says Mr. Sardi. When these 15 million people read the government checklist, many are going to ask to have their cataracts removed rather than go on living with limited sight," he says.. Government efforts to ration cataract care will likely backfire, predicts Sardi.

The new guidelines for cataract care also suggest that the only valid method of testing for glare, the most common symptom caused by cataracts, is to take cataract patients outdoors and test their vision in sunlight. "It is well known that ultraviolet sun rays worsen glare problems among cataract patients. Cataract patients exhibit better vision when tested indoors in the doctor's office under artificial light compared to sunlight. Conducting a glare test in outdoor sunlight could increase the number of candidates for cataract surgery by as much as 35-70% says Sardi. A newly released General Accounting Office (GAO) report confirms that more cataract patients in Texas had problems with glare and other cataract symptoms than patients in Massachusetts. Ultraviolet sun rays are stronger in southern latitudes and there are more days of clear sunshine in Southern environments, notes Mr. Sardi.

"Senior Americans who move to sunnier climates for their retirement years may be increasing their need for a cataract operation," notes Mr. Sardi.

According to government data, approximately 50% of the U.S. population aged 65 to 74 have cataracts, and the prevalence of cataracts increases to over 70% among adults over age 75. This amounts to 19.8 million U.S. adults who have cataracts, or 37 million eyes with cloudy natural lenses. U.S. eye surgeons only remove 1.8 million cataracts annually, which represents less than 5% of the candidates for the operation, says Mr. Sardi.

Government guidelines for cataract care, which have yet to be issued to the majority of U.S. cataract surgeons, suggest that there is a significant amount of unnecessary cataract care. The General Accounting Office estimates the amount of needless cataract care ranges from 2.5 to 24% depending on how long a patient will wait before electing to undergo cataract extraction. The American Academy of Ophthalmology disputes these numbers, claiming the government used poor research methods to come up with their estimates.
Government bureaucrats asked patients who had undergone cataract surgery to evaluate their own symptoms and quality of vision, rather than utilizing standardized vision tests performed in a doctor's office.

Sardi indicates we now have different branches of the government disagreeing with each other. A report conducted by the Inspector General's office conflicts with the General Accounting Office report. The Inspector General's Office found an insignificant amount of premature cataract care.

Sardi says he conducted a mail survey of prospective surgical candidates for cataract care and found that 25% of the time eye surgeons didn't recommend cataract removal as soon as they could have. "The data I collected showed that U.S. eye surgeons were oftentimes slow to recommend cataract removal, even when the patients had indicated they had given up an activity due to their limited vision," says Mr. Sardi.

With modern cataract care patients do not have to wait till cataracts become ripe, nor do they have to give up activities they enjoy or need to perform, such as driving, sewing, reading, or playing golf, says Sardi.

The Agency for Health Care Policy Research indicates a delay in cataract removal does not jeopardize the outcome of surgery. Mr. Sardi says this advice is wrong. "While there is no rush to have most cataracts removed, waiting too long to undergo cataract removal makes an eye operation more difficult to perform," he says.

The older you are the smaller the pupil opening of your eyes, says Mr. Sardi. Cataracts are removed through the pupil opening and thus smaller pupils make it more difficult to remove cataracts. With age cataracts are harder and more difficult to remove. Older cataract patients tend to have plaques within the eye that cannot be removed by cataract removal. These plaques can be removed with a laser, but patients usually have to wait 6 to 12 months following cataract surgery for laser treatment. With advancing age patients are more likely to develop arthritis and breathing problems which makes it more difficult to lay still on an operating table.

"It's obvious the government has issued these guidelines to ration eye care, not to give the best medical advice to cataract patients," says Mr. Sardi. The American Academy of Ophthalmology indicates that the patient, "not a set of government guidelines," is the best judge of when cataract surgery should be performed.

Mr. Sardi says the government has ignored data which shows that undetected and untreated cataracts actually increase the cost of health care. A recent report, published in the Journal of the American Geriatrics Society, indicates the rate of hip fracture among older Americans increases by three times when patients elect to live with mild cataracts (20/30 to 20/80 vision) in one eye. The cost of two cataract operations is only one-fifth of what it costs to repair a fractured hip, notes Mr. Sardi.

The Society of Geriatric Ophthalmology indicates poor vision caused cataracts may account for 10% of premature admissions to nursing homes. The cost of one year of nursing home care far exceeds the cost of cataract care.

A report issued by the National Research Council indicates cataracts are the major cause of auto accidents among older drivers and that "older Americans with cataracts may be inclined to drive for many years with vision worse than 20/40 vision before they notice they have cataracts."

Living with limited sight caused by cataracts has its drawbacks and the need for a cataract operation should be carefully discussed with an experienced eye surgeon," advises Mr. Sardi. ####

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GENERAL ACCOUNTING OFFICE USES FLAWED METHODS IN CATARACT OUTCOMES REPORT

A newly published General Accounting Office survey of post-surgical cataract patients indicates:

--Unnecessary or premature cataract surgery ranges from 2.5 to 24%, depending upon the degree of visual problems patients will tolerate before electing to undergo cataract removal.

--If patients ignore symptoms caused by cataracts, such as glare, double vision and blurred vision, and wait until they can identify an activity they can no longer perform well, such as driving, reading or watching TV, then the rate of early cataract care is 6%.

--For every one percent of cataract care approximately $34 million is spent by the Medicare program as a whole. Thus a 6% rate of premature cataract care amounts to $200 million in Medicare spending.

--Only 70-74%% of post-surgical cataract patients reported improvements in symptoms and functional vision (reading, watching TV and driving) following their cataract operation, while 12-18% reported the outcome of their cataract operation was mixed, with some conditions improving and others worsening. Five percent said their vision was uniformly worse following their cataract operation.

--1-2% of post-surgical patients said they experienced severe pain, and 7-8% moderate pain, in the immediate period following their cataract operation. Five percent said they developed a post-operative infection and 13% said they had to undergo a second procedure.

The data for the GAO report was obtained by mail survey of 1,488 cataract patients who had undergone an eye operation in four states (California, Massachusetts, Texas and Pennsylvania).

This GAO survey is seriously flawed. Here's why:

Patients were surveyed as soon as 4.8 months (median 7.4 months) following their cataract operation when a cloudy membrane may be interfering with the outcome of their operation. While 13% of postoperative patients had undergone a secondary procedure (including YAG laser surgery to remove hazy membranes), it is not clear if patients who complained that their vision had not improved following their cataract operation were in need of YAG laser treatment. If these patients were to be surveyed 12 months following their operation the results might be significantly different, with far fewer patients indicating cataract surgery had not improved their sight. This major flaw in the survey renders most of the outcome data invalid.

The GAO outcomes data is used to determine rates of unnecessary care. The GAO claims that patients who do not experience improved sight should not have undergone an early-stage cataract operation. Patients who reported little or no symptoms or functional visual problems prior to surgery were more likely to state they did not experience improvement or that their vision was worse. According to the GAO report, nearly all parameters of visual handicap (symptoms and functional loss) would need to be severe in order to justify the need for a cataract operation.

While some patients claimed their vision hadn't improved following cataract removal, the GAO failed to confirm these subjective reports by reviewing the patient's medical record. Older adults may inaccurately evaluate the quality of their postoperative vision when asked to recollect what their vision was like prior to surgery.

The GAO study only emphasized "needless or premature" cataract care, rather than looking at how many people waited too long to undergo the operation. The GAO report revealed that 33-50% of cataract patients waited till they experienced severe symptoms or difficulties with activities before electing to have their cataracts removed. Thus many patients may have waited too long to have their cataracts removed. How many cataract patients needlessly gave up driving or other activities is unknown. Once older Americans give up activities they are less likely to resume them, figuring they are just too old, say geriatricians.

While the government estimates six percent, or somewhere between 78,000-108,000 cataract operations are premature, other studies estimate 15-16 million senior Americans have undetected cataracts.

The GAO report narrowly addresses how cataract care can be rationed or delayed. The government does not estimate how many older Americans who delay cataract care will give up driving an automobile, how many will fall and fracture a hip, how many will prematurely enter nursing homes, or will needlessly give up activities that they enjoy. A primary objective of the U.S. Public Health Service and the AARP Healthy Older Adults 2000 campaign is to reduce hip fractures among older Americans. The rate of hip fracture dramatically increases with only mild vision changes caused by cataracts in one eye.

The GAO survey of post-surgical cataract patients totally relied upon elderly patients to accurately evaluate the outcome of their operation while ignoring standardized vision tests performed by eye physicians.

If the GAO would go and check the medical records of the patients who indicated their vision hadn't improved since their cataract operation they would find thet the majority either had undetected retinal disease, had need for YAG laser treatment, or actually had measurably better vision by visual acuity testing.

Sensitivity to glare was the symptom most likely to worsen after cataract surgery, reported by 26% of the patients. Glare problems may be related to other conditions such as dry eye, rather than the cataract operation itself. Preoperatively 20-32% of cataract patients stated they had mild to severe "itching," a common symptom of dry eye, but dry eye symptoms were only noted among 13-18% of patients postoperatively. Dry eye symptoms decreased from 14.8% immediately following surgery to 4.3% two months postoperatively. The provision of post-operative sun goggles and soothing eye drops would alleviate most glare and dry eye problems.

The GAO report was also biased because it eliminated from the survey 3% of patients who underwent intracapsular cataract extraction. The intracapsular cataract extraction method is known to increase the risk of retinal detachment and other serious complications following cataract extraction. While the GAO expressed interest in improving the quality of cataract care, they oddly removed from review eye surgeons who perform an oumoded method of cataract extraction.

The government is looking at surgical outcomes, and eye surgeons are going to have to pay attention to their surgical results. Postoperative problems, such as infections, secondary procedures and re-hospitalization, as well as the time required for patients to resume normal daily activities, will be used as markers for the quality of cataract care.

The GAO report indicates 23.1% of patients were able to function normally immediately following their cataract operation, and 13.5% claimed they fully resumed normal activities within one day of their operation. In contrast, 10.5% of patients had to wait more than a month to begin to function normally, and 22.5% waited that long before they said they were back to normal. Eye surgeons who do not perform small incision cataract removal are going to be hard-pressed to show good outcomes data to the government.

The GAO indicates it will continue to conduct surveys and seek methods to reduce the demand for cataract care, despite the growing population of older Americans, 95% of whom have vision changes caused by cataracts. ####

Critical Analysis of the Clinical Practice Guideline

Cataract in Adults: Management of Functional Impairment, Clinical Practice Guideline Number 4. Rockville, MD - U.S. Dept. of Health & Human Services, Public Health Service, Agency for Health Care Policy Research, AHCPR Pub. No. 93-0542. Feb. 1993

By Bill Sardi, President
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Revised

[References to exact citations in the cataract guidelines below are provided with the page where they can be found within the document.]

Introduction

The Clinical practice guideline for cataract care is a 226-page document developed by an 18-member panel under the Omnibus Budget Reconciliation Act (Public Law 101-239). The guideline took two years to develop and reviewed almost 8000 scientific papers as reference material. The entire document cost taxpayers over $1 million. This document has been published, along with a brochure outlining the guideline's recommendations to patients, before eye surgeons have had a chance to become familiar with its contents.

Oddly, these guidelines were developed without the participation of any major high volume cataract specialist, even though a majority of the cataract operations performed in the U.S. are performed by "high volume" surgeons, who may be in a better position to contribute to the development of such guidelines.

In some important areas these guidelines fail miserably to advise senior Americans about the positives and negatives concerning modern cataract care. These guidelines also appear to have a hidden agenda, that of attacking high volume eye surgeons who advertise their services.

The only redeeming section of the guideline is that it will be reviewed and updated every two years.

Granted, government has a considerable investment in cataract care and in ensuring that senior Americans, who undergo the majority of cataract operations, are adequately informed and cared for.

Government documents concerning cataract care have, in the past, been sources of misinformation. The Fraud, Waste, and Abuse report concerning cataract care, published by the House Aging Committee in 1985 (then headed by Congressman Claude Pepper) was the first to factitiously report that 30% of cataract care was unnecessary. This false report was based upon questionable data provided by Blue Cross in a very small group of patients who underwent surgery of all kinds (not just cataract surgery). The definition of "unnecessary" cataract care was never provided.

The 1985 report said: "Leading health and medical experts have reported that 23-36% of all cataract surgery may be unnecessary or represent overutilization." No references were provided for this false claim. Insurance companies, like Blue Cross, would have an incentive to spread false rumors about unnecessary cataract care. This false statement was never challenged by the news media.

Over the following decade the news press continued to erroneously print that 30% of cataract care was needless. Years later, even though the Inspector General's Office found there was no significant amount of needless cataract care, this falsity has never been erased from the minds of the public and government officials. The myth of unnecessary cataract care has roots in the current guidelines on cataract care. [Refer to the report OEI-09-88-01000, "OUTPATIENT SURGERY MEDICAL NECESSITY AND QUALITY OF CARE, Office of Inspector General September 1990.]

While cataract care is a significant part of the entire Medicare budget and has come under repeated scrutiny in the past decade, the guidelines fail to indicate any need for their development. What will actually change now that the guidelines have been published? Are patients any better informed because of this document?

Rationing in disguise

Despite the fact that the guidelines state that *"it would be unacceptable to ration cataract treatment so that some individuals in valid need of surgery would be excluded* [Page 10]," the AHCPR chose to emphasize in its press release concerning the cataract guidelines that *"physicians and patients should not rush into cataract surgery if glasses or visual aids can provide satisfactory functional vision."* [HHS New Release 2/25/93] In essence, this was a "rationing" statement that should be considered with suspicion by senior Americans. This statement furthered the myth that needless cataract care is being performed.

In fact, there is data which reveals that some patients wait too long to have their cataracts removed. In a study of 123 cataract patients, 25 were tested for contrast and glare acuities and should have been operated on earlier. While the panel cited the reference for this report, they failed to mention its major conclusion. [Eye 4: 712-17, 1990]

Some experts recommend that cataract surgery be performed before a patient has adapted to a life of poor vision, because it is difficult to regain the skills that have been lost. [Acta Ophthalmologica 61: 392-96, 1983]

In a survey of people who were living with cataracts, 71% of the time their eye doctor had not recommended surgery even though they had given up an important activity in their lives due to their limited vision. Many eye surgeons fail to recommend cataract surgery in a timely manner. [LIVING WITH CATARACTS, Eye Communications 1991]

The Society of Geriatric Ophthalmology published a list of benefits that elderly cataracts would derive from early vs. late cataract surgery. These included fewer postoperative complications, better immediate postoperative vision, reduced difficulty of surgery, and delay of onset of dependency. [PRESCRIPTION FOR CHANGE: CATARACT CARE 1990 Society of Geriatric Ophthalmology 1990.]

The AHCPR chose to emphasize outmoded methods (stronger eyeglass prescriptions and magnifiers) of managing visual problems caused by cataracts that were relied upon decades ago, which are useless for distance (driving) vision, and which may actually increase the cost of cataract care (frequent eyeglass prescriptions). Placing a magnifying lens over a cloudy cataractous lens does little to improve sight. The cloudy lens needs to be removed and a clear lens inserted in its place.

In Defense of Medical Advertising

An underlying assumption of this guideline is that premature or unnecessary care is being provided on a massive scale, and that doctors who utilize overt marketing techniques to recruit patients may be largely responsible for reputed unnecessary cataract care.

The guidelines state [p. 11] that: "*the panel was concerned by reports of some eye care providers using high-powered marketing to recruit patients who might not need cataract surgery.*" No references were provided concerning these untoward "reports" concerning medical marketing, which is not consistent with the methodology of the report as a whole.

Network TV news reporters have begun to investigate various marketing techniques utilized by eye surgeons. These investigations have stemmed from the release of the AHCPR guidelines and reveal the real purpose of the cataract guidelines: to scare patients away from needed cataract care.

The fact is, there are variable levels of skill and experience among the nation's 8,000+ cataract surgeons. The public is largely ignorant when it comes to even understanding what cataracts are, let alone how they should be treated. A Louis Harris & Associates poll published in March of 1990 indicates 61% of U.S. adults are not familiar cataracts and 15 million have undiagnosed cataracts. [20/20 September 1990, page 44] Another report indicates only 16% of U.S. adults know what a cataract is. [Ophthalmology Times March 1, 1992, page 1]

Advertising and other marketing methods play a role in informing the public about the most modern methods of performing cataract care and in helping achieve various health goals for senior Americans (reduced rate of hip fractures, reduced nursing home admissions, reduced auto accidents among elderly auto drivers, etc.).

In a survey of patients who were living with cataracts, only 4% could correctly identify the modern methods of cataract removal. [LIVING WITH CATARACTS, Eye Communications, 1991]

Experienced eye surgeons who perform the most modern methods of cataract removal should continue to utilize internal and external methods of informing the public about the modern advances being made in cataract care. <u>The fact that the AHCPR government guidelines fail to adequately inform the public about these advances further promotes the need for experienced eye surgeons to utilize ethical marketing methods</u>.

A more detailed analysis of the deficiencies of the cataract guidelines is provided below.

<u>Critical Analysis</u>

1. The guidelines fail to recognize that cataract patients are frequently unaware of visual symptoms caused by cataracts, or that cataracts are the cause of their visual problems. The guidelines [Page 71] indicate: "*The patient's decision to undergo surgery depends upon his or her own assessment of visual disability (impact on reading, driving).... and perception of the impact of the disability upon lifestyle (loss of independence, loss of income).*"

Cataract patients are oftentimes unaware that they have cataracts and/or fail to link their functional and visual problems with cataracts. An example of this is the elderly female who over-dyes her hair and it appears "blue" to others but grey in her eyes. Many patients discover they have cataracts only after they have fallen and fractured a hip. Other patients are completely unaware their vision doesn't meet drivers license renewal requirements.

In summary, it is the doctor who must counsel the patient so that they understand the ramifications of their cataract problem. The patient does not usually understand the impact of cataracts upon their own life without the doctor's assistance.

2. The guidelines failed to address the three most common reasons why senior Americans fail to obtain timely, quality cataract care. Fear, ignorance and cost keep many elderly adults from achieving their full visual potential through modern cataract care.

A recent survey of blacks in East Baltimore revealed that many older Americans are living needlessly with limited vision caused by cataracts, a completely curable eye problem. [The Baltimore Sun, February , 1990]

Some patients may deny that they have visual problems in fear that they will lose their drivers license. Some patients fearful of cataract surgery may delay care, to the detriment of their health.

3. The guidelines failed to warn prospective cataract patients of the increased risk they face from an outmoded form of cataract surgery that is still being performed by a small number of U.S. eye surgeons.

While the guidelines quickly warned of possible ethical problems and overutilization of care by eye surgeons who advertise their services, the guidelines overlooked the obvious hazard posed by eye surgeons who perform the intracapsular method of cataract extraction.

Every work day in America 80 cataracts are extracted by the intracapsular cataract extraction method, a technique that utilizes an ice probe to pull the cloudy cataract from the eye. The only mention that the AHCPR guidelines make of intracapsular cataract extraction is in the glossary of terms [Page 164].

In 1981 an estimated 90% of U.S. eye surgeons used the intracapsular method of removing cataracts (Mt. Sinai J. Medicine 48: 539-42, 1981) Today only a small number of eye surgeons still utilize this archaic method of cataract removal.

In a study sponsored by the Health Care Financing Administration, researchers found that the intracapsular method of removing cataracts increased the risk of retinal detachment by over 80% when compared to the extracapsular and phacoemulsification methods. (Investigative Ophthalmology, ARVO Abstracts, March 15, 1990)

The AHCPR guidelines failed to warn prospective cataract patients of the increased risks posed by intracapsular cataract extraction. All patients whose eye surgeon recommends an intracapsular cataract extraction should seek a second opinion from an experienced eye surgeon.

The guidelines unfairly portray so-called "high volume" eye surgeons as irresponsible and unethical, but completely ignores backward eye surgeons who place their patients at increased risk of complications every time they remove a cataract.

4. The guidelines fail to recognize the importance of including optometrists in the postsurgical care team. An estimated one out of four cataract patients have chosen an optometrist to be their eye doctor.

Prior to inclusion of optometry in the Medicare program, optometrists would often hold on to their cataract patients for a prolonged period of time before referring them for surgery. This delay tactic, prompted by the concern that the optometrist would lose care of the patient, resulted in increased costs to patients (more eye exams and eyeglass prescriptions).

The guidelines also questioned high volume eye surgeons' responsibility for delegating postoperative care to

optometrists. There was little mention made to the obvious conflict between the Medicare code which permits optometrists to perform and bill for postoperative care, and the guidelines, which cast some doubt about the safety of postoperative care provided by optometrists.

The fact that advances in cataract care have shortened the postoperative period and that modern cataract care improves sight quickly, lends to the use of optometrists and nurses for postoperative care.

Eye surgeons are obligated to provide postoperative care because they are paid a global fee for surgery and all postoperative care. When optometrists do provide postoperative care, they bill Medicare for their services and these fees are deducted from the surgeon's fee. (Medicare actually saves a small amount of money when optometrists provide post-op care.)

If there is something unethical or medically harmful concerning optometrists providing post-operative care then the Medicare code should be changed. The cataract guidelines made no such recommendation.

The guidelines suggest that the postoperative eye exam be comprised of the following:

1. Test for intraocular pressure.

2. Evaluation of lens implant position.

3. Evaluation of inflammation.

4. Test for visual acuity.

5. Evaluation of the surgical wound.

All of these clinical evaluations listed above are capably performed by optometrists whose licensure and training covers these tasks. This is not to say that optometrists have the same training and skills of ophthalmologists.

Most eye surgeons in the U.S. perform initial postoperative examinations and then return the patients to the optometrists who originally referred them for surgery.

5. The guidelines did not address the medicolegal concerns of cataract surgeons. While the AHCPR guidelines did not recommend routine glare, contrast, retinal function testing, and endothelial cell counts, it failed to note the need for these tests by eye surgeons who must defend themselves before peer review organizations, Medicare carriers, State Medical Review boards, and in cases of malpractice litigation.

6. The guidelines continued to call for a "gold standard" in regards to preoperative vision tests, but failed to adequately provide a comprehensive discussion of this topic.

The guidelines failed to adequately review the two environments which cataract patients live in. That is, daylight and night vision.

Daylight vision with cataracts is best evaluated under exact outdoor conditions. The spectral output of the sun contains ultraviolet rays which are known to increase the glare symptoms among cataract patients. Tests performed inside the doctor's office do not generally test vision in sunlight. Thus, most of the indoor tests may bias visual tests among cataract patients, falsely indicating their vision is better outdoors than it really is in sunlight.

Night vision tests really require the wearing of red glasses for 30 minutes or more to fully dilate the pupil and adapt the retina to dim light (scotopic vision). Diminished night vision and night roadway glare are probably the most common visual complaints of cataract patients. Such testing is impractical for testing in a doctor's office.

Thus most of the time vision tests falsely indicate the cataract patient has better vision than is actually experienced outdoors during the day or night.

Testing vision in outdoor sunlight, as the cataract guidelines suggest, would INCREASE the number of surgical candidates and would promote earlier cataract care, which is contrary to the recommendations of the published guidelines.

The guidelines failed to address other tests for cataract disability, namely light transmission (lens opacity meter), depth perception tests, and color temperature.

7. The guidelines continued to cite the drawbacks of glare and contrast testing for evaluation of preoperative vision, yet failed to note that many of the references utilized in the AHCPR guidelines concluded that Snellen visual acuity testing is an inaccurate and outdated method of evaluating cataract vision. Even the visual acuity tests (Snellen charts) utilized in most clinicians offices are not preferred by the Food & Drug Administration for clinical tests of cataract lens implants. Why do the AHCPR cataract guidelines continue to rely solely upon a vision test that was developed over a century ago?

8. The guidelines fail to recognize that there are differences in the experience and skill levels of eye surgeons. The chances of cataract surgery resulting in vision of 20/40 or better range from 80% to 100% [Page 89]. Patients should know that there are differing odds on seeing 20/40 following a cataract operation, and that the skill (technique) and experience of the eye surgeon may be important factors.

9. The guidelines fail to recognize the mobility of senior Americans. The cataract guideline suggests patients are better served by obtaining care in their own communities [Page 40].

Many millions of senior adults live in motor homes, rural areas, or travel to vacation areas like Florida. These patients may decide to obtain cataract care anywhere they desire. For example, some patients may feel they are obtaining better care at the Mayo Clinic, and travel there for care. These freedoms are a part of the American medical system. It is difficult to understand the intent of this part of the guidelines. Are cataract surgeons supposed to tell out-of-town patients to go back home for their cataract care? What problem is this section of the guidelines attempting to solve?

10. The guidelines fail to recognize the desires of patients. Some cataract patients with diseased retinas may insist that an eye surgeon remove a cataract in an attempt to improve their vision. If these patients are adequately informed of their decreased chances of improved sight, and fully understand the risks of cataract removal, cataract removal may be appropriate in an attempt to achieve vision better than 20/200 (legal blindness). Patients who can see better than 20/200 are still able to perform many daily living tasks and are able to play cards with an over-sized deck.

11. In all cases, the fact that a surgical consent form must be signed, renders moot the statement that eye surgeons only recommend surgery to patients who desire the operation.

12. The guidelines failed to evaluate the issue of undiagnosed and untreated cataracts upon healthcare costs and safety of senior Americans. Untreated cataracts may significantly increase health care costs and have other

negative financial consequences. The economy as a whole suffers when adults must retire prematurely, limit their driving, and cut back on leisure time activities.

A National Research Council report advocates that older automobile drivers be screened for visual problems in an attempt to reduce accident rates among older drivers. While 60% of the driving population can pass the 20/40 standard without corrective lenses, 37% require updated prescriptions for corrective eyewear and 3% require referral for medical and surgical eye care. Four-fifths of those who fail to achieve 20/40 vision in a screening exam will be able to obtain 20/20 vision with proper medical and surgical eye care. The recommendation by the Transportation Research Board to screen elderly drivers for cataracts and other eye abnormalities runs contrary to the recommendations of the Cataract Guidelines.

The National Research Council report says:

"*A significant percentage of the older driver population could potentially benefit from the implementation of routine contrast sensitivity vision screening. These data indicate, for example, that 5 to 7 percent of those aged 65 and older suffer from cataract. On the basis of 1980 census data this figure translates into nearly 2 million individuals. Most of these individuals continue to drive despite markedly diminished visual capacity. Indeed, cataract is often not detected and diagnosed until it has progressed to such an advanced state that even high-contrast acuity is impaired. As a result, the typical older driver with cataract could be expected to experience several years on the road with significantly impaired vision before diagnosis. Early detection and management of cataracts could result in significant improvements in driver safety, efficiency, and mobility.*" (Source: TRANSPORTATION IN AN AGING SOCIETY, National Research Council, Volume 2, Special report 218, 1988, pp. 310 & 348-49.)

A report in the Journal of the American Geriatrics Society indicates the risk of hip fracture increases by as much as three times by vision of 20/30 to 20/80 in one eye only (Journal American Geriatrics Society 37:495-500, 1989) The cost of repairing a fractured hip exceed $25,000. Reducing hip fractures is the major agenda of the AARP Healthy Older Adults 2000 Project.

The Cataract Guidelines run contrary to the preventive health goals outlined by the Public Health Service, the AARP and the National Research Council.

The Society of Geriatric Ophthalmology produced a report that indicated undiagnosed and untreated cataracts may be a primary cause of needless nursing home admissions, at a cost of billions of dollars. (PRESCRIPTION FOR CHANGE: CATARACT CARE 1990)

13. The guidelines failed to cite that eye surgeons are dramatically changing their method of cataract removal and now prefer the phacoemulsification method. There must be good clinical reason why more and more eye surgeons are learning this method of cataract removal. Small incision cataract removal results in prompt visual rehabilitation and faster wound healing.

14. Because of insufficient data, the guidelines panel could draw no conclusions from the medical literature concerning numerous topics. Therefore the panel relied upon the previously published *Preferred Practice Patterns* by the American Academy of Ophthalmology (AAO). The AHCPR guideline states that there was insignificant opposition to these *Preferred Practice Patterns* developed by the AAO [Page 71]. Therefore they chose to utilize them. This statement ignores the fact that many eye surgeons opposed the AAO's *Preferred Practice Pattern*. Opposition to the AAO's *Preferred Practice Patterns* was voiced in many trade journals by leading eye surgeons and organizations within ophthalmology. The statement that there was no significant opposition to the AAO's *Preferred Practice Patterns* is a bald-faced misrepresentation of the facts.

15. The panel suggests screening for functional disability, but does not describe how this should be accomplished, leaving clinicians to guess what this means. [Page 72]

16. The guidelines indicate Extracapsular or Phacoemulsification methods of cataract surgery are equally effective methods of restoring vision to the 20/15 - 20/40 level when vision is measured a year following surgery, but the guidelines failed to indicate how quickly visual rehabilitation occurs with these methods. Small incision methods of performing cataract extraction often result in improved sight immediately, whereas patients who undergo extracapsular cataract extraction may wait days to weeks before experiencing improved sight. Prompt visual rehabilitation may be important to patients who need to renew a drivers license or who care for others in the home.

17. The guidelines failed to recognize that many elderly cataract patients may not be fully literate and able to understand consent forms or postoperative instructions. An estimated 30% of senior Americans cannot fully understand all of the words printed on the front page of a newspaper.

18. The guidelines fail to recognize that there are cost-saving alternatives for cataract care. A cataract extraction performed in an ambulatory surgical center costs approximately $1000 less than when performed in a hospital. President Bill Clinton wants to reduce health care spending by $50 billion over the next five years. If there were incentives for patients to undergo cataract operations at ambulatory surgical centers Medicare would save approximately $5 billion over a five-year period. Previously there were incentives for patients to undergo care at ambulatory surgical centers but they were abandoned when Medicare felt they increased the demand for cataract care. Senior Americans should be aware they can significantly help to hold health care costs down by obtaining cataract care at ambulatory surgical centers. The guidelines failed to mention this important fact.

19. The guidelines failed to show a need for their development or that any real change in clinical practice will be made now that these guidelines are cast in stone. Such outcomes should be prospective and planned, rather than hoped for.

20. The guidelines failed to outline to clinicians what penalties there are for practicing outside of these guidelines.

21. The guidelines failed to recognize the dispute between eye surgeons who perform more advanced methods of cataract surgery and who are more likely to advertise their services, and low-volume eye surgeons who continue to claim the marketing techniques employed by high volume eye surgeons are unethical. In a survey of eye surgeons, 36% believed advertising was unethical, and this figure rose to 81% among eye surgeons who perform less than 10 cataract operations per month.[ETHICS IN CATARACT CARE, Eye Communications 1989]

The rivalries within ophthalmology have fallen on an open ear with government and the news media, who have spent millions of dollars to chase false claims of unnecessary cataract care, purported to be performed exclusively by high volume eye surgeons. The Federal government spent over $25 million for a peer review program for cataract surgery that yielded only 1/10th of one percent unnecessary cataract care. The program to pre-review cataract surgery cost more money than it saved.

When will government and the news media recognize there is an explosion in the demand for cataract care which will not stop for many years to come? In England there is no medical advertising and yet they are experiencing a rapid demand for lens implants and cataract care. [Eye 5: 369-72, 1991]

22. The guidelines fail to indicate why clinicians at large were not permitted to review the guidelines prior to publication.

Conclusions

Denis M. O'Day MD, the panel's head, asks: *"How well will the guidelines work to ensure appropriate, effective care?"* The answer is: It miserably fails to accomplish anything meaningful to patients.

Dr. O'Day states: *"At the heart of the guideline development is the welfare of the patient in a health care system increasingly pulled in many directions by a variety of interests, not all of which are concerned about the patient or his or her well-being."* (O'Day, D.M., Archives of Ophthalmology, Volume 111, March 1993, p. 317-18.)

Who are these bogey men who are not concerned about patients? Why doesn't Dr. O'Day come out an openly express his prejudices. Why does he piously view the work of his committee without submitting it for critical review? Isn't peer review one of the essentials of medicine? All medical journals require peer review. Why this document avoided such review remains at the heart of the prejudices inherent within the panel of "experts" who developed it.

It is not a crime to make a profit removing cataracts in the United States. Nor is it a crime to ethically conduct medical marketing. More and more patients seek out those eye surgeons who perform the most advanced cataract removal techniques.

The fact that an eye surgeon performs high volume surgery, or that he or she advertises their services, does not mean that the surgeon provides inadequate care for patients or that he or she is unethical.

Instead of headlines which should read: *"20% of cataract surgery performed too late, increasing social welfare costs,"* the headlines falsely read *"Don't rush into cataract surgery."* The government propaganda machine continues to propagate false information concerning cataract care in a futile attempt to reduce the demand for cataract care.

Who is orchestrating the release of the AHCPR Cataract Guidelines to the news media without review by U.S. eye surgeons? Who is orchestrating the soon-to-be-released General Accounting Office report that is critical of marketing techniques used by U.S. eye surgeons? Why does the thrill-seeking news media not catch on to the fact they are being manipulated for the sake of sensational stories about unnecessary cataract care? Why doesn't the news media have the guts to correct their mistakes once they have published them?

U.S. eye surgeons need to be aware of the growing body of misinformation that is being published about cataract care, some with the government's name attached to it. Eye surgeons also need to be aware of the growing number of "witch hunts" now underway at state levels to single out and punish high-volume eye surgeons for performing "unnecessary" cataract surgery.

In conclusion, the AHCPR Cataract Guideline as written is not a friendly document to U.S. eye surgeons nor to the many millions of senior Americans who have cataracts. This guideline requires extensive review and revision, hopefully by a different panel of experts who more adequately represent the visual needs of senior adults.

Excellent references which were not cited by the AHCPR panel are:

Aquavella, J.V., "Cataract surgery: Who's A Candidate?, Patient Care, August 15, 1986, pp. 46-81.

Leibowitz H.M., "When to refer the elderly patient with cataract," Hospital Practice, March 30, 1987, pp. 19-37.

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April 28, 1993

Honorable David Pryor
Special Committee on Aging
U.S. Senate
Washington DC 20510

Re: Recent workshop on cataract care

These questions need answered

Recently the Agency for Health Care Policy Research (AHCPR) headed by Jarrett Clinton MD, released a set of government guidelines for cataract care written by a committee headed by Denis O'Day MD of Vanderbilt University. This was followed by a General Accounting Office (GAO) survey which attempted to indicate how often the timing of cataract surgery was appropriate. Both the AHCPR cataract guidelines and the GAO report gave the false impression that there is a significant amount of unnecessary cataract care being provided by the nation's eye surgeons.

There are serious flaws in the AHCPR and GAO reports which are only revealed by answering the following questions:

Why did the GAO eliminate from their survey patients who had undergone the outmoded intracapsular cataract extraction? Why weren't senior Americans warned of this relatively dangerous form of cataract operation that is still performed 3% of the time?

> GAO's Eric Peterson said: "*We're not excluding from consideration cataract operations that were done by certain types of physicians. It was basically everybody.*" (Testimony at Senate Aging Committee) Yet the GAO report openly admits they did not survey patients who underwent the intracapsular form of cataract removal. Was this a misrepresentation?

Why did the AHCPR falsely indicate that their cataract guidelines were developed in meetings that were open to the public when they were in fact written and developed in secret?

Why did the GAO pre-release its report covertly to the news media, and to the Prime Time Live ABC-TV staff, before the official release of the document at the Senate Aging Committee workshop? Was this an attempt to spread government propaganda to the news media before it could be refuted by authorities in the know? Isn't an unknowing news media being made a pawn to spread the gospel of rationing cataract care?

Why is there no data released on the amount of undetected and untreated cataracts? According to one report, an estimated 15-16 million Americans have undetected cataracts.

Why is there only an emphasis on premature cataract surgery? According to the GAO data, 33-50% of cataract patients may have waited too long before electing to undergo an eye operation.

Why does the GAO presume that older Americans only participate in three activities, watching TV, driving an automobile and reading? These were the only functional parameters studied by the GAO in their survey of patients who underwent cataract surgery. When Dr. Earl Steinberg of John Hopkins University added ten more functional activities for review he came up with a 2% inappropriate rate of cataract surgery, not the 16% or the 24% that the GAO indicated.

> Harvey Brenner PhD of Johns Hopkins says: *"We have no discussion of work problems, mental health problems, household problems, accidents, and the entire range of human problems emanating from poor vision caused by cataracts."*

Why is no prognosis data provided as to the problem of living with poor vision caused by cataracts? In other words, there "*is no assessment of what would happen to patients if treatment were to be delayed.*" (Quote: Harvey Brenner PhD, Professor of health policy and management, Johns Hopkins University. A report in the Journal of the American Geriatrics Society indicates the rate of hip fracture will increase by over three times if elderly patients continue to live with mildly poor vision (20/30 to 20/80) in one eye only. The Society of Geriatric Ophthalmology estimates 10% of nursing home admissions may be related to undiagnosed and untreated cataracts.

Why does the GAO entirely rely upon the patient to judge whether their vision is improved after cataract surgery, falsely indicating up to 24% of patients were dissatisfied with the result of their operation, when the Food & Drug Administration has conducted vast studies that show when cataracts are removed, and there is no accompanying eye problem, that lens implants are 94-98% reliable in restoring 20/40 vision? Why didn't the GAO sample doctor's records to see if they confirmed the patient's own claims of dissatisfaction after cataract removal?

> *"Objective tests often show that patients have visual improvement that exceeds what the patients perceive."*
> *Tom Hutchinson MD, American Academy of Ophthalmology*

Why did the GAO ask postoperative cataract patients if their vision was improved following cataract extraction without separating out those the responses from patients who hadn't undergone YAG laser treatment? A hazy membrane often develops following cataract surgery and those patients who have not had this hazy film removed may complain their vision is poor. It is unfair for the GAO to survey patients 7.4 months following cataract surgery when they may still be in need of YAG laser treatment.

Why does the GAO report indicate there is a range of premature cataract surgery, ranging from 2.5 to 24% depending upon how long the patient is willing to wait till they suffer severe functional impairment, and then say "*we have no idea how much inappropriate cataract surgery is being performed.*" (Quote: Eleanor Chelimsky, GAO office, at the Senate Aging Committee Hearing) With the GAO statement above, aren't they admitting that their agency has wasted five years and a considerable amount of money to come up with invalid data?

Why wasn't it mentioned that the GAO report, which indicates a range of premature cataract care from 2.5 to 24%, conflicts with the findings of the Inspector General's Office which found less than 2% of cataract care was inappropriate?

Why did the GAO fail to note that among the 2.5% of cataract patients who they claim only had mild visual symptoms prior to surgery, 50% of these patients noted their vision improved. How could vision improve among patients who had been identified as having undergone unnecessary cataract care?

Why didn't anyone challenge the GAO as to why they essentially duplicated a report conducted by the Inspector General's Office issued in 1990? Isn't this redundant government? (See report: Outpatient Surgery Medical Necessity and Quality of Care, OEI-09-88-01000, September 1990)

What wasn't it mentioned that the government spent over $50 million in its Peer Review project, to preauthorize all cataract operations, and found only 2/10ths of one percent of cases were needless? The Peer Review program was abandoned because it cost more money than it saved. How much more money will government waste in a futile attempt to limit the amount of cataract care being performed?

Why isn't the issue of cataract prevention placed on the agenda? There are known risk factors for cataracts that can be controlled, such as diabetes, nutrition, sunlight exposure. Isn't prevention, not physician review, the appropriate direction for government to go to get control over health care costs, including cataract care?

Why do government researchers ignore epidemiological data which reveals that the rate of cataract surgery per capita does not generally exceed the visual acuity deficit caused by cataracts? The well-known Framingham Eye Study reveals that 3.3% of adults experience worse than 20/30 vision from cataracts, which amounts to 138 million senior adults who experience a drop in their vision caused by cataracts. U.S. eye surgeons only remove 1.8 million cataracts annually. Thus less than 5% of available candidates undergo cataract removal.

Why did the AHCPR release the cataract guidelines to over 1000 members of the news media and to the public before U.S. eye surgeons could acquire a copy and be informed as to its contents? Why are eye surgeons now being asked to conform to these guidelines by state Medical Boards and other agencies when they haven't even had an opportunity to read the guidelines? Why are voluntary cataract guidelines being used by State Medical Boards to seek penalties and sanctions against eye surgeons?

Why did the GAO report indicate 23.1% of cataract patients could "begin to function normally" less than a day following their eye operation, while 21.5% of patients could "not fully get back to normal" one or more months following their operation, but never inquire WHY? It is well known that small-incision methods of cataract care promote faster healing and quicker visual rehabilitation.

Why do we continually fail to inform the public about the who performs the best type of cataract care? Since the GAO attempted to define "needless" cataract care by the percentage of patients who didn't experience a good outcome within a year of their operation, then it should be noted that surgeons who perform "wide incision" cataract removal would have a higher rate of "unnecessary" care than "small-incision" cataract surgeons.

Summary:

There has been more government waste and fraud in attempting to find "unnecessary cataract care" than actual cases of confirmed needless eye care.

That government has misled the nation's news media, and thus the American public, that U.S. eye surgeons perform massive amounts of needless care.

Government will not correct misinformation it sends to the nation's news media. The AHCPR issued a "second press release" describing their cataract guidelines but failed to inform the news media why they re-drafted their statement (which was strongly criticized for rationing eye care). Neither did the government correct its false statement of 25-30% unnecessary cataract care when it issued a report from the floor of the House Aging Committee in 1985.

That government is covertly rationing cataract care.

The American public is still poorly informed about the best type of cataract care available and is not advised of increased risks posed by outmoded forms of cataract extraction.

Preventive measures are not emphasized nor encouraged by government.

Conclusions:

Statement of Senator Burns from Wyoming on his recent cataract operation: "*No matter what these folks at GAO say, it's worth the money. I put up with it for three to four years. My father had two cataracts taken off and I don't think my dad could have operated an automobile into his 80's or had any quality of life without having his cataracts removed.*"

Statement of AHCPR panel member Stephen Obstbaum MD: "*As a reasonably well informed member of the panel, an ethical practitioner and a spokesman for ophthalmology who has championed the goals of the guidelines, I feel betrayed by the intentional subversion of the purposes of this document.*"

Statement of Thomas Hutchinson MD, American Academy of Ophthalmology: "*It is a tragedy to our elderly that its government will be heard as saying we're looking at 24% inappropriate surgery, when nothing is further from reality.*"

Official press release of the American Academy of Ophthalmology: "*The individual ---- not a set of government guidelines ---- is the best judge of when cataract surgery is appropriate.*"

Bill Sardi

SOCIETY OF GERIATRIC OPHTHALMOLOGY
Advocates for Timely, Quality Vision Care
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April 29, 1993

Honorable David Pryor
Special Committee on Aging
U.S. Senate
Washington, DC 320510

Dear Senator Pryor:

Thank you for allowing the April 21, 1993 workshop concerning cataract surgery to hear how weak the GAO report on cataract surgery is. It was a pleasure to know you were told that the design of the study was so poor that this "paper could not expect to be published" in any scientific journal.

We understand that the GAO would like to reduce the amount of cataract surgery. We oppose both unnecessary surgery and the rationing of needed cataract care. The secrecy in developing the GAO report and the cataract guidelines, the design of the GAO study, and the inappropriate conclusions of the GAO study made one believe the objective of the GAO was to ration cataract care by letting the patient live with varying amounts of visual impairment.

The Johns Hopkins study by Dr. Brenner "Vision Change and Quality of Life in the Elderly" clearly shows that the quality of life would decrease for all those patients who the GAO would force to live with their cataract.

Enclosed is our press release, the story of my wife's cataract surgery and a comparison of the AHCPR's guidelines with more modern guidelines. Please include this letter and the enclosed materials in the Senate Aging Committee's report.

Very truly yours,

John W. Norris, M.D.

JWN:rj
Enclosure

P.S. Dr. Earl Steinberg's comparison of the PORT study with the GAO study clearly showed that unnecessary cataract surgery is rare and the GAO conclusions were inappropriate.

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Release: April 21, 1993
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Re: Senate Aging Committee's
Cataract Workshop

Washington, DC – Today's General Accounting Office report to the Senate Aging Committee that a percentage of the highly successful cataract surgical implant procedure is inappropriate is "economically and socially irresponsible" says the leading proponent for orderly eye care. The Society of Geriatric Ophthalmology (SGO) said the Aging Committee/GAO effort only continues the unsubstantiated pattern of government reports designed to ration vision care, undermine the patient doctor relationship and frighten senior citizens concerning needed cataract surgery.

Past allegations dating back to the 1985 Pepper Committee hearing have always been proven to be severely exaggerated. A 1990 Inspector General investigation of the 30% unnecessary surgery claim of the Pepper hearing instead showed that 98.3% was indeed appropriate. The IG spokesman then said that its study showed surprisingly good results and that the vast, vast majority of cataract cases are of high quality and medically necessary.

Again, in 1991, when Medicare decided to discontinue its costly $50 million mandatory cataract pre-certification program, it used peer review organization data showing that only 0.02% of over two million such procedures were considered questionable.

Untreated cataracts remain one of the leading causes of blindness in the United States. When the government released the AHCPR's cataract guidelines on February 25, 1993, the guidelines declared that screening for cataracts was not appropriate unless the patient complains. "One of the major reasons cataracts remain a leading cause of blindness is that seniors don't complain because they mistake the problems caused by cataracts as an aging condition they must live with", says the SGO. This attempt to stop screenings was denounced by several groups of ophthalmologists. The AHCPR's guidelines were labeled as a government attempt to ration cataract care. The question of whether the government would seek to ration care by limiting screening for breast cancer, diabetes, high blood pressure and other problems lead to a discussion of whether the government really is committed to preventive care and early detection or in just controlling cost.

A Johns Hopkins study, "Vision Change and Quality of Life in the Elderly" will be published in the May 1993 Archives of Ophthalmology. It concludes that "many types of functional degeneration observed in older populations, ..., can be slowed, or even reversed, when vision function is improved". As vision declines the report shows that driving, in home activities, community activities, mental health and life satisfaction declines, but can improve with appropriate vision care. This is a major reason why Americans should not be forced to live with cataracts.

Studies have shown that American women are three times more likely to fracture a hip with a mild cataract in one eye, that 44% of those fracturing their hip were not wearing needed corrective eyeware, that auto accidents increase with poor vision and that a significant number of nursing home admissions are related to treatable cataracts and could be avoided by treatment.

Most cataracts develop because the lens of the eye becomes cloudy with aging. The AHCPR's guidelines show that 75% of those over 65 have some clouding of the lens or cataracts. Less than 2% of cataracts are operated on each year.

Outpatient surgery and the government cutting fees for cataract care have reduced the cost of each cataract operation by 50% in the last seven years. The cost of cataract care exceeds $3 billion annually. The cost of untreated cataracts resulting in hip and other fractures, unnecessary nursing home admissions, auto accidents, hospitalizations due to medication errors and economic isolation is unknown.

Instead of focusing on why cataracts are a leading cause of blindness in this country and how much not treating cataracts costs in terms of human suffering and economic loss to the country the GAO focuses on care that is given. One has to question if the GAO started its investigation before the report was complete. Did the GAO and AHCPR work together to develop a report which would help ration cataract care?

The Society of Geriatric Ophthalmology (SGO) requested that the Senate Committee on Aging develop a legislative program that will help Americans retain their visual independence.

Suggestions given are:

1) A bill to require a complete eye examination before every nursing home admission.

2) A bill to require vision testing to retain a driver's license at ages 65, 70, 75, 80 and every two years thereafter. Over ninety percent of potential problems would be eliminated by simply having a person get new glasses.

3) Funding of visual rehabilitation services for the partially sighted under Medicare and Medicaid.

4) Funding of effective outreach programs such as eye screenings to ensure that operable cataracts are no longer a leading cause of blindness in the United States.

5) Support of the FDA against special interest groups and allow full labeling of the UV protection in sunglasses.

6) Stress prevention of cataracts by educating the public about the need to protect themselves against the cataract risks caused by UV radiation, smoking and poor nutrition.

7) Support the development of high technology intraocular lens so that the intraocular lenses remains a United States industry.

"It is time for us to act economically and socially responsibly in order to stop operable cataracts from being a burden our elderly must suffer", said John W. Norris, MD, past president of the SGO. "We hope the Committee on Aging will provide leadership in this area instead of focusing on this misleading GAO report".

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Medical Postscript

A 1992 copyrighted publication of EYE COMMUNICATIONS 1241 West Ninth Street Upland, CA. 91786

The Carolyn Norris Cataract Story

Why I had my cataracts removed when my vision was 20/20

Carolyn Norris, married to a cataract surgeon for nearly 30 years, could read nearly all the letters on an eye chart, yet she told her husband that she needed a cataract operation. For the millions of American adults whose vision is affected by cataracts, they may benefit from reading the story below.

Cataracts are common, especially as adults grow older. But for the millions of adults who have cataracts the question is when to have them removed.

Carolyn Norris, bright, vibrant wife of an ophthalmologist, first heard she had cataracts when her husband examined her eyes three years ago: "He told me then he had detected changes in the lenses of my eyes some 20 years ago but hadn't told me till now," says Carolyn.

Using conventional methods of testing vision, Carolyn Norris' cataracts would be called mild. But the problems they caused were quite debilitating. The vision in Carolyn's left eye was 20/25 and 20/20 in her right eye. So she could see nearly all of the letters on the eye chart.

"I think my husband was a bit shocked to see cataracts growing so rapidly inside my eyes. But unfortunately it wasn't till three years ago that I began to experience symptoms," says Carolyn.

Her family has a long history of cataracts. Her mother had cataracts removed from both eyes before she reached 50 years of age. Carolyn's aunts, uncles, brother and younger sister also have cataracts.

"I knew I was going to have to have them out sooner or later," says Carolyn, who progressively lost her ability to read normal size type in books, gave up her needlepoint, avoided driving at night, and struggled with her tennis game.

Carolyn says that living with cataracts was no fun. She experienced two falls. The first fall, which occurred on a staircase while talking to someone else, she discounted as a normal accident. "Anybody could have missed a step," she says. But four months later she fell again, and this time with no distractions. "I just couldn't see that the sidewalk was uneven and I took a tumble."

Carolyn Norris had fooled herself into believing she could live with her cataracts a while longer. However an incident that occurred while driving changed her thinking.

"I was driving down a tree-lined street on a sunny day and a United Parcel truck was parked by the side of the road. The driver was crossing the street. He was in the shadows, and I didn't see him until I was alongside him. I could have run over him. It was then that I realized I couldn't see and had to do something about it," says Carolyn Norris.

John W. Norris MD , Carolyn Norris

While Carolyn had glare problems in the sun she experienced even more glare on overcast days when playing tennis. A tennis ball looked like a grey blur. Different lighting conditions caused differing problems.

"Your vision gets worse so gradually that you think this is normal. Others don't understand what you can't see," says Carolyn.

Continued next page

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"Really, for years, every time I was in a room with a large window I couldn't face the sunlight and see anyone's face. Faces looked like a silhouette," she says. "I always sat with my back to windows."

"The day before the operation I was challenged by another physician at the Eye Institute. He said: 'You are such an active woman. How could you think of having cataract surgery?'"

I said, "Keep your thoughts to yourself. I can't read or drive."

The day of surgery went smoothly for Carolyn, though she admits that days prior to her operation she visited her husband's operating room to brush up on how cataract operations were performed these days.

"Really, there was no pain, and it was amazing. A few hours after the operation I was taking off my eye patch to see my granddaughter who was born the night before."

"I couldn't believe the difference in my vision between one eye and the other. Before the operation I thought the air was clear. With lens implants the air now appeared bluish. In my other eye with the cataract the air appeared brownish."

"As I compared my vision, straight lines on the edge of a door were fuzzy, but in the eye with the lens implant the door was sharp and clear."

Carolyn recalls her feelings when she first began experiencing her renewed sight. **"I said to my husband: 'I don't know why you didn't tell me I needed to undergo surgery sooner instead of making me struggle with my sight.'"**

"I thought I would wait for my second eye operation till there was another breakthrough in cataract surgery. But my non-dominant eye was operated on and my two eyes were fighting each other. I was still having trouble with my tennis game and with my eyeglass prescription."

"After my first cataract was removed I was back driving right away, but when I was in a glare situation I would just close my right (unoperated) eye." When she experienced glare this left Carolyn with obscured vision on one side.

"I screamed in astonishment one morning when I was able to see myself in the mirror of my dressing table. It has a light in front of it and it would always create a fog in my vision. Now it was clear. After cataract surgery, there were lots of little surprises like this."

"My husband made me aware that I had given up needlepoint some years earlier. I hadn't realized I had given up my needlepoint because of my fading vision. I thought I was too busy for it. Now, after the operation, I resumed my needlepoint. For the first time I could see the subtle differences in colors of yarn."

Carolyn's advice to eye doctors: "Now, after the operation, I would tell doctors to listen to their patients more. Patients say they are having minor vision problems and the doctor doesn't perceive these as symptoms of cataracts or that they significantly interfere with living."

"I could have lived without cataract surgery, but the quality of my life would definitely not be the same," says Carolyn.

"My younger sister had her cataracts removed last year, but my brother who also has cataracts doesn't think he is ready yet." A lot of people's eyes are ready for cataract surgery but they're avoiding the thought of an eye operation."

For Carolyn an added bonus of the operation was less dependency upon eyeglasses. "I still need eyeglasses when I read, but when I drive or go out for the evening on social occasions I don't need glasses at all."

Carolyn sums up her thoughts for others who have cataracts: "Before a cataract operation if there was some way of briefly experiencing what you would see after cataract removal, I think a lot more people would opt to have their cataracts removed sooner. **I just didn't realize what I was missing, and I didn't fully understand how my cataracts were affecting my life.**"

•The American Geriatrics Society reports that a mild cataract in one eye can increase the risk of sustaining a fall resulting in a hip fracture by as much as three times. Fixing a broken hip costs $25,000 and upwards, many times more than cataract removal operations.

CATARACTS

Cataracts form behind the pupil of the eye, inside the normally clear "aspirin size" lens. A cloudy cataract is not solely an indication that a person needs to have them removed. But when cataracts cause visual problems consultation with an ophthalmologist is suggested. In many instances adults have cataracts that are interfering with their daily activities but fail to connect their problems with cataracts.

As we learn in the CAROLYN NORRIS CATARACT STORY, it's not the size of the cataract nor the ability to read an eye chart that dictates when to have cataracts removed.

Continued from back page

this, Carolyn's preoperative refraction was -2.50 -0.50 Axis 75, and postoperatively -0.75 -1.00 Axis 75 in her left eye.)

"Her vision was so good it was right then, while we were driving home from seeing our grandchild, that Carolyn started getting on my case for not having recommended cataract surgery sooner," recalls Dr. Norris.

"Before the operation Carolyn was struggling with her sight. She does all the financial and computer work at the Eye Institute and she was under a lot of stress to produce end of the year reports, and she was making all kinds of excuses as to why she wasn't getting things done on time. After the operation she whizzed through her tasks."

As delighted as Carolyn was with her sight, she was having trouble making her two eyes work together. With contrast testing her vision had improved from 20/100 to 20/20 in her operated eye, but she now had 20/100 vision by contrast testing in her right eye. To make matters worse, she was still 2.50 diopters nearsighted in her unoperated eye, and she couldn't find an eyeglass prescription that made her happy."

By June she couldn't tolerate it any more. On July 1 she underwent her second cataract operation. "I was far less nervous about the whole thing the second time around," says Dr. Norris.

The day after the second eye operation Carolyn's vision was nearly 20/20 with a little bit of astigmatism. (In doctor's language, she ended up with an eyeglass prescription in her left eye of PLANO -0.50 Axis 100.)

Says Dr. Norris: **"For Carolyn, her cataract operations were like the excitement of Christmas.** For me it was not only a joy, but also a learning process about cataracts."

"I don't think I understood how important the dominant eye is. I have been doing mono vision (implanting lenses in one eye for near vision and the other for distance vision) for a long time. I didn't really remember patients complaining about having the non-dominant eye for distance and the dominant eye for near vision. After Carolyn's surgery and her problems with dominance, I started to realize that the patients whose dominant eye is corrected for near after surgery compensate for the problem by wearing their glasses more often than those whose dominant eye is fixed for distance.

"The thing that startled me was how much Carolyn had given up. Because we were watching her cataracts progress so slowly and she had been so involved in the practice, I thought I knew the full extent of her disability. After surgery, it seemed that every day she found another thing she had stopped doing."

The third thing that was interesting to watch was how pleased Carolyn was to be slightly nearsighted after the first eye was operated on. After the second surgery she had much better vision and was disappointed that the first eye was nearsighted. Three months later she wishes she was slightly more nearsighted so that she would be less dependent on reading glasses. She is really so happy with the sharpness of her vision that she would be delighted with any of these results."

"My advice for doctors has always been to ask more questions of their cataract patients. Are you satisfied with your eyeglass prescription? Do you have problems driving? Are you able to see well at night, in the sun, see steps, read your checkbook, Bible, medicine labels? Have you taken a fall? Now I'm not so sure we can adequately question them because the patients don't even realize what they have lost. I still think probing questions like these are useful since they help patients make a connection between their ailments and having cataracts," says Dr. Norris.

"Once patients realize that we understand their problem and we can help, they usually elect to schedule surgery on their own," he says.

"We see patients all the time at the Eye Institute who have been going from doctor to doctor complaining about their sight or their eyeglasses. **The patients don't really connect their symptoms with cataracts** and their doctors think the patient has mild cataracts that are not interfering with their lifestyles. Carolyn proved a point that we were already aware of. It is only AFTER having cataracts removed that the patient gets angry at their doctor because their doctor hadn't told them sooner that they needed a cataract operation," says Dr. Norris. **"Carolyn firmly believes she should have scheduled her cataract surgery one year earlier,"** he adds.

"Carolyn firmly believes she should have scheduled her cataract surgery one year earlier." John W. Norris M.D.

For reprints of the CAROLYN NORRIS CATARACT STORY contact Eye Communications 1241 West Ninth Street Upland, California 91786
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The Cataract Connection

Should eye surgeons recommend that cataracts be removed when vision is 20/20?

Should eye surgeons recommend that cataracts be removed when vision is 20/20?

Recently John W. Norris M.D., South Orange, New Jersey eye surgeon, made such a recommendation, and the patient was his wife, Carolyn.

"I don't commonly tell people who can still see the 20/20 line on the eye chart that they need cataract surgery," says Dr. Norris. "I had known for a number of years that Carolyn had a particular type of cataract (posterior subcapsular) and now knew the cataract was causing problems."

"We chose the most experienced surgeon in the area to do Carolyn's surgery. The day I drove Carolyn to the Eye Center I was nervous inside."

Cataracts are nothing new to John W. Norris M.D. He began removing them in 1969 and performed his first lens implant operation on March 17, 1973, years before most eye surgeons began to regularly perform the modern type of cataract care.

Twenty-one years since beginning medical practice and some 12,000 cataract operations later, Dr. Norris was examining his wife Carolyn's eyes and telling her she had cataracts.

"When I first went into medical practice, I examined Carolyn's eyes so I could test the examination equipment I had just purchased. It was then that I first noticed that Carolyn had opacities throughout the natural lenses of her eyes. I didn't tell her at that time."

"When she first began complaining of symptoms, about three years ago, I told her about the cataracts. Later on I told her she had a type of cataract that would probably be ready for surgery by the end of the year."

"I knew her left eye was the main problem. She was experiencing depth perception problems in tennis, had difficulty reading and I had no doubt she would be ready for surgery by January. **I was wrong**. When we went to Florida in January of 1991 Carolyn still did not have significant symptoms."

Carolyn next had her vision tested at the American Academy of Ophthalmology Meeting in Anaheim in November of 1991 and her vision was 20/16 in her right eye and 20/25 in the left eye. On the contrast test her vision was 20/40 in each eye. "I believe that this test was consistent with her vision problems," said Dr. Norris.

"In January of 1992 Carolyn announced she was ready for the operation. I re- tested her vision with a contrast tester. Her vision had faded to 20/70 in her right eye and 20/100 in her left eye. **But remember, on the standard eye chart she still registered near-perfect sight!"**

The eye chart falsely indicated Carolyn Norris' vision was as good as a hawk's. In real life, under different lighting conditions (low contrast), her vision was miserable.

"The day I drove Carolyn to the Eye Center I was nervous inside. I calmed down a bit during the operation," he says. "She underwent the **no-stitch cataract removal** technique with a lens implant. I insisted the surgeon use a six millimeter lens implant and add one stitch to help control astigmatism. **Her vision was 20/16 immediately following the operation,"** he notes.

Within hours of the operation Carolyn was being rushed to another hospital, only this occasion was the birth of her grandchild. Under Dr. Norris' supervision, Carolyn removed her eye patch so she could see her new granddaughter.

"Carolyn was really doubly thrilled," recalls Dr. Norris. "She had just seen her newborn grandchild and was experiencing her new found sight following her cataract operation."

"We were driving back from the hospital and she kept covering one eye and comparing the vision in her eye with the lens implant with her other eye with a cataract. **She was like a little kid, amazed at the clarity and ability to see the road signs in the distance without glasses."**

Preoperatively Carolyn was nearsighted. Her eyeglass prescription had gone from 2.50 diopters of myopia to less than one diopter immediately after the operation. (For doctors reading

Continued on page 3

CATARACT GUIDELINES COMPARED

	AHCPR Guidelines	Subspecialists' Guidelines
Developers	Academic dominated. Broad based but vision scientists and sub-specialists not represented.	Clinically dominated. Most are cataract subspecialists who developed today's procedures.
Cost To Public	$1,000,000	$0
Information Cut Off Deadline	December 31, 1990. Rare exceptions.	March 1993.
Supporters	American Academy of Ophthalmology (AAO)*	American College of Eye Surgeons
	Association of University Professors of Ophthalmology*+	Outpatient Ophthalmic Surgical Society
	Ophthalmic Society of Registered Nurses*+	Society of Geriatric Ophthalmology
	American College of Surgeons+	Society for Excellence in Eye Care
	National Society to Prevent Blindness+	Society of Ophthalmic Anesthesiologist
	Alliance for Agency Research	

*All have same address
+AHCPR Panel, and/or AAO members dominate advisory board

CATARACT GUIDELINES COMPARED

	AHCPR Guidelines	Subspecialists' Guidelines
Major Objections	Doesn't meet current standards of cataract care. Drafted so that rationing could be imposed.	Since written by Cataract surgeons, it could be self-serving.
Weakness	Over 85% of report based on opinions of those with limited clinical experience. Snellen visual acuity only objective test.	Opinion rather than scientific. Report not reviewed by government or others before release.
Indication For Surgery	Patient needs for functional improvement. Glare and Contrast testing not indicated.	Patient needs for functional improvement. Should be documented by Glare and Contrast testing when indicated.
Snellen Guidelines	20/50 unless symptoms indicate need when Snellen vision is better than 20/50. Measures high contrast only.	20/50 unless symptoms indicate need when Snellen vision is better than 20/50. Measures high contrast only.
Glare Testing	Not proven, but should be used to document glare symptoms if 20/40 or better.	Glare testing demonstrates value when glare symptoms and vision 20/40 or better.
Constrast Sensitivity	Not proven and not stand alone test.	Compliments Snellen since it measures the low contrast that Snellen doesn't.
Preoperative Medical Evaluation	Always Indicated.	Varies with health of patient.

CATARACT GUIDELINES COMPARED

	AHCPR Guidelines	Subspecialists' Guidelines
Type of Surgery	Intraocular and Phacoemulsification have same long term results.	Both types give good long term results. Phacoemulsification give faster short term results with less astigmatism.
Benefits of Cataract Surgery	High.	High.
Risk	Minimal and same in both studies.	Minimal and same in both studies.
Surgeon's Post Operative Responsibility	Entire recovery period but may delegate to ophthalmologists, optometrists and others to deliver care.	Entire recovery period but may delegate to ophthalmologist, optometrists and others to deliver care.
Post Operative Visits	1 day, 1 week, 1 month 2 months.	1 day and again within 1 month. Other visits as needed.
Yag Laser	Valuable when symptoms indicate need.	Valuable when symptoms indicate need.
Screenings To Detect Cataracts	Not appropriate unless patient complains of symptoms. This is the reason rationing is feared since the report documents that untreated cataracts are a leading cause of blindness.	Valuable to prevent auto accidents, falls, and hip fractures, etc. Late diagnosis leads to more complications associated with surgery.

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CATARACT GUIDELINES COMPARED

	AHCPR Guidelines	Subspecialists' Guidelines
Rehabilitation	Warning that doctor of his responsibility to ask probing questions because patients fail to report symptoms (opposite of screening concept above).	Essentially the same.
Ethics	No stand against outmoded care or failure to provide timely care.	Not specifically addressed.
Misinformation claims	American Academy of Ophthalmology's cataract guidelines used for many decisions because of claims that while the report is not scientifically supported, they have not been opposed (Page 71). The truth is that they are opposed and this is the reason that subspecialists' guidelines were written. Peer Review Organizations opposing guidelines not listed as Peer Reviewers.	The terms "several studies to demonstrate", "evidence to prove", etc. are occasionally used to imply accepted practice is scientifically proven.
Research Recommendations	Many excellent recommendations	Not addressed

InSight Reports

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May 3, 1993

Portia Porter Mittelman
Director
Senate Aging Committee
G-31 SDOB
Washington, DC 20510

Dear Ms. Mittleman:

Re; Cataract Surgery Appropriateness

Regarding the record for the above referenced April 21 hearings, I am submitting various material relative to the Cataract Practice Guideline developed under the auspices of the Public Health Service Agency for Health Care Policy Research (AHCPR).

While it may be unique for a media organization to submit material for inclusion in a hearing record, I do so for a very disturbing reason; mis-information provided your committee by the the AHCPR.

The following half-truths were provided your hearings:

o Stating that the cataract guideline is scientific in nature because over 8,000 pieces of medical literature were reviewed when, in fact, the guideline states it found little in the search to help (medical science answered only two of its 61 questions) and went further to recommend 29 areas of needed research. Bottom line is that the guidelines -- abhorrent as they are to clinical ophthalmology -- were framed based on the judgment of academicians.

o Stating that the cataract guideline panel is highly credentialed, but failing to say the panel is void of clinicians, void of surgeons who do an average of 200 or more procedures per year, void of surgeons who use modern surgical procedures and technologies, void of industry representatives and void of vision scientists.

o Stating that the cataract panel met in open session when, in reality, it's one 2-hour open session offered no agenda items to be addressed. In fact, the panel did all of its work in unannounced, closed sessions, contrary to the Federal Advisory Committee Act.

o Stating that the final draft document was subject to significant peer review before publication when, despite requests and pleas from major ophthalmologic organizations for this opportunity, there was no more than limited, if any, peer review.

o Stating that the cataract guideline had received significant public endorsement -- you named the American Academy of Ophthalmology (AAO) and five others like university professors and ophthalmic nurses, four of which endorsed solely because of AAO arm-twisting. In fact, you failed to mention the significant on-the-record refusals to endorse the guideline which were sent to the AHCPR by today's clinicians as represented by the American Society of Cataract & Refractive Surgery, American College of Eye Surgeons, American Association of Retired People, Outpatient Ophthalmic Surgery Society, Society for Excellence in Eyecare, and Society of Geriatric Ophthalmology.

I can't even speculate on AHCPR's reasons for failing to be totally honest with a Committee of the U.S. Senate, itself tying to fashion meaningful public policy. One-sided, devious half-truths have no place is this environment. I trust you agree.

Thank you for your cooperation.

Sincerely,

Charlea Sonneborn

encl.

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